Contributions to Risk Management in the Public Sector

Doctoral Thesis by

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Preface

This thesis is submitted in fulfilment of the requirements for the degree of Doctor of Philosophy (PhD) in Risk Management and Societal Safety at the University of Stavanger, Faculty of Social Sciences. The research presented in this thesis was carried out between March 2003 and November 2007. The PhD scholarship has been a part of a recruitment program, and I am grateful to the Norwegian Ministry of Education and Research for the funding. Since January 2005, I have been affiliated with the research project: "*Patent safety – Managing undesired events within healthcare*," established as a collaboration between the University of Stavanger (UiS) and Stavanger University Hospital (SUH). I am grateful to SUH for partly funding my PhD project. Moreover, I would like to express my gratitude to the Department of Media, Culture, and Social Sciences (UiS). The department funded an additional period of six months that was crucial for completing my PhD. Today, I am delighted to pay my department and faculty back in the form of this thesis.

I would like to thank all informants representing the municipalities, the hospital, the patient ombudsman, and the regulatory authorities for taking their time to participate in the PhD project.

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Stavanger, November 2007

Siri Wiig

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Summary

Accidents and threats have always been present in society, but the increasing complexity and interconnectedness within society, including the public sector, contribute to the emergence of new types of risk and more complex causalities. The ability to understand the emergence of risk, and to manage and control risk is a prerequisite for individuals, organizations, and society to survive and operate safely. Over the past years the role of the state, as a regulator and risk manager, has increased. The management and control of risk within the state takes place at many system levels, ranging from policy level to street level bureaucrats by means of laws, rules, and instructions. Each level can influence the others in an integrated and tightly coupled control system. These levels constitute subsystems within the state and offer different organizational interfaces or points of contacts between the organizational subsystem and its members. Managing risk and preventing accidents in the public sector therefore depend on activities and interfaces among actors at different system levels.

This thesis draws attention to multilevel risk management processes in two public sectors: public healthcare and municipalities (local government). The risk management processes covered are those ensuring patient safety in the specialized healthcare sector and municipal emergency management in the municipal sector. The thesis explores and analyzes how the society establishes regimes to regulate and manage risk within the public sector, by applying the socio-technical system perspective as a framework. This approach allows the shifting of levels of analysis within the socio-technical system involved in public risk management and gives rise to issues like regulatory regimes; tools and strategies applied in controlling and managing risk; understanding the emergence of and adaptation to, risks; information flow and learning processes among system levels; and characteristics of organizational interfaces among different agencies and institutions of national, regional, and local character of importance for public risk management processes.

The main focus of the thesis is the organizational interfaces involved in risk management processes in the public sector. The overall research problem is: How can organizational interfaces across system levels explain risk management processes in the public sector? Several theoretical contributions in risk, regulation, and organizational studies are applied to explore and interpret these organizational interfaces. A qualitative research strategy was chosen to provide insight into organizational matters, risk management processes, and discourses within different risk regulation regimes. A multiple embedded case study was conducted and the cases were selected according to

a most dissimilar approach, in order to emphasize the contrasts among them. The cases covering specialized healthcare and municipal emergency management were chosen due to their variance in risk profiles, complexity, and size involving different risk regulation regimes.

In four research articles, the thesis documents that organizational interfaces across system levels can explain risk management processes in the public sector. Two articles describe organizational interfaces across the entire socio-technical system; how risk amplification and attenuation and learning function in the interfaces; and how regulatory enforcement influences risk management processes. Two articles investigate how the organizational interface between regulators and regulatees affects public risk management; how different enforcement strategies promote or counteract learning processes; and how a system or an individual focus in enforcement activities makes different contributions to risk management processes.

Results in Article I documented that different system levels in Norwegian healthcare depend on each other in the process of error prevention. The contextual descriptions of the entire healthcare risk management system revealed that learning from errors is sporadic, individual and occurs separately within the single system levels, with limited information and knowledge exchange among system levels. The healthcare system's ability to prevent and learn from errors was negatively affected by reforms initiated at the governmental level. Structural reforms concerning hospital financing and institutional management altered important framework conditions at all system levels. The reforms resulted in a compound pressure between efficiency and safety at hospital, management, staff, and work operation levels. The effects were time pressure, stress, increased workload, and understaffing, all of which had a negative impact on the learning conditions within and across system levels. Results also show that the regulator-regulatee interface has limited impact on the ability to learn from errors in the healthcare system.

Article II documented how risk regulation strategies in municipal emergency management contributed to information exchange and learning within the regulated municipalities. Results demonstrated that activities categorized as compliance enforcement strategies contributed to second-order learning processes and defined regulation as a learning process. Activities within deterrence enforcement strategies were categorized as short-term adjustments and not defined as a learning process. Learning barriers such as time pressure, competing demands, and financial circumstances were identified in the regulator-regulatee interface, complicating the improvement of risk management processes.

Article III demonstrated that the regulatory activities within specialized healthcare that were rooted in a system perspective promote openness and dialogue affecting patient safety more positively than activities that were rooted in an individual perspective. The individual perspective contributes to underreporting, fear of sanctions, hampering openness, discussion, and information exchange. From a risk management perspective, the approaches within the regulator-regulatee interface need improvement if they are to move systematic regulatory activities towards a system perspective, and to emphasize incidental and advisory activities more strongly.

Article IV revealed differences in the degree of heterogeneous versus homogenous risk perception across system levels between specialized healthcare and municipal emergency management. Findings showed that risk perception differs among employees and officials within various system levels of the two risk regulation regimes. Risks are amplified and attenuated throughout the socio-technical system through risk management processes depending on interaction among humans, organizations, and regulators; external pressure from public and organized interests; technological changes, and financial circumstances causing compound pressure between safety and efficiency. The social amplification and attenuation of risks were more prominent in the specialized healthcare regime, counteracting a common conceptualization of risk throughout the regime.

To conclude, the study of two most dissimilar cases has demonstrated that contrasts between structures (e.g. legal framework, institutional design, framework conditions, roles, and responsibilities) and processes (e.g. interaction among subsystems, regulatory practice, information flow, conflicting objectives) provided new insight into how organizational interfaces add explanatory power to the success or failure of risk management processes, with potential relevance beyond municipal emergency management and specialized healthcare. Socio-technical systems involving a comprehensive legal framework, defined roles and responsibilities; complex institutional design; and tightly coupled interaction processes among diverse occupational groups create multiple subsystems and organizational interfaces in which risk management processes are highly dependent on common conceptualization of risk, sufficient communication mechanisms, and continuous information flow across the organizational interfaces to succeed. Socio-technical systems involving less structural complexity; fewer legally predefined roles and responsibilities; and more loosely coupled interaction processes create fewer interfaces between subsystems and their members, implying better conditions for communication processes, information flow, and oversight. This leaves the organizational interfaces less prone to contribute to complicate the risk management processes. This thesis found

that a multilevel understanding of organizational interfaces requires an integration of a broad theoretical perspective in order to interpret their implications at different system levels, ranging from the governmental level in the blunt end to street level bureaucrats in the sharp end. Thus, the research results create a foundation for further theoretical and empirical development, and suggest focal areas in order to develop an understanding of public risk management as a multilevel process.

Part I

1 Introduction

This thesis is about risk management in the public sector. To set the agenda, a brief introduction to the historical development of risk research is provided along with the parallel development of risk regulation research. Characteristics of the public sector and risk management processes therein, form the background of the research purpose and problem of the thesis.

1.1 Background

Risk has always been an inherent feature of human existence, and the field of risk research started when people started reflecting on the possibility of their own death and contemplating actions to avoid dangerous situations (Aven, 2003; OECD, 2003a,b; Renn, 1998; Rosa, 1998). However, the systematic scientific attempts to study risks in society, is more recent (Renn, 1998; Hale & Hovden, 1998). Risk research has been influenced by a range of theoretical perspectives and methodological approaches (Tayler-Gooby & Zinn, 2006). Multiple academic disciplines such as technology, economy, psychology, sociology, and anthropology have contributed to the evolution of risk research and provided new knowledge on improving the management of risk. Yet, no common definition of risk exists, neither in the sciences nor in the public. Nevertheless, Renn (1992; 1998) argues that all risk concepts have one aspect in common: the distinction between reality and possibility. If the future were either predetermined or independent of present human activities, the concept of risk would make no sense (Renn, 1992; 1998).

Early models of risk management were linear and static. Hazards were depicted as escaping energy or substances that could be managed by the design of barriers. However, the models turned out to be insufficient due to the dynamic nature of risk management, which still remains a major challenge for risk research. Systems are dynamic and include several feedback and adaptation loops, as revealed when risk research started incorporating human and organizational aspects (Hale, 2006; Hale & Hovden, 1998). Risk issues are now understood as complex social issues, in which a variety of stakeholders have divergent – though equally legitimate – points of view. How these diverse views are considered and integrated into policy making, how risk and decisions are communicated, and how the media and society at large receive and apply information have been integrated into risk management (OECD, 2003b). Today many risk researchers direct focus to contextual aspects and changes imposed on the actors at different societal levels and even beyond national borders in a globalized world. During the past ten years, the concept of risk governance has emerged, referring to the actions, processes, laws, traditions, and institutions by which decisions about

risk are prepared, taken, and implemented. The adoption of the governance concept in risk research is a response to complexity and changes. It meets the need for a more systemic integrative understanding of technological and social aspects of risk, risk perception, and regulation regimes, and it tries to cope with the interplay among economic, political, scientific and civil society actors involved in governance processes (Renn, 2005; 2007; Renn & Klinke, 2004).

In parallel with the development of risk research, the field of risk regulation and the nature of the philosophy of regulation have changed as an aspect of New Public Management reforms (Hale, 2006; Loefstedt, 2004; Gunningham, 1999; Reason, 1997; Hovden, 1998). The last thirty years have preached self-regulation (e.g. Baldwin & Cave, 1999; Ayres & Braithwaite, 1992), reduction of government intervention, and directed the responsibility to the risk creator in order to establish sufficient risk management systems to be inspected according to a goal-based regulation, replacing the prior detailed rule-based regulation (Hood & Jones, 1996; Kirwan et al., 2002; Hale, 2006). However, not everyone has been a proponent of self-regulation regimes, such as small and middle-sized enterprises in industrial sector and small municipalities in the public sector (Lindøe & Hansen, 2000). They have pleaded for clear rules as a way to lighten the burden of risk management. The shift from rule- to goal-based regulation also constitutes a challenge to regulators and inspectors. They need tools and strategies that enable them to assess whether or not companies and sectors or interacting actors in complex systems can be trusted to be self-regulating (Hale, 2006; Reason, 1997; Svedung & Rasmussen, 1998). Along with a shift in regulation philosophy, aspects such as out-sourcing, cost-cutting, the break up of monopoly companies have challenged the ability of anyone to grasp the big picture (Hale, 2006).

1.2 New Public Management (NPM)

Worldwide, the public sector has undergone tremendous changes over the past twenty years. New Public Management (NPM) forms the backdrop of these change processes (Osborne & McLaughlin, 2002; Power, 1999; Hood, 1991). NPM was based upon a sharp critique of bureaucracy as the organizing principle within the public sector (Osborne & McLaughlin, 2002), and on the concern with the ability of the public sector to provide the economical, efficient, and effective provision of public services (Huges, 2003). NPM comprises a variety of overlapping elements and a cluster of ideas borrowed from the conceptual framework of private sector administrative practice (Power, 1999). Even though there has been some discussion over the precise

nature of NPM (Dunleavy & Hood, 1994; Flynn, 2002), the main aspects of NPM involve (Hood, 1991; Osborne & McLaughlin 2002):

- A focus on hands-on and entrepreneurial management, as opposed to the traditional bureaucratic focus of the public administrator
- Explicit standards and measures of performance
- An emphasis on output controls
- The importance of the disaggregation and decentralization of public services
- Greater competition in the public sector
- A stress on private styles of management and their superiority
- The provision of discipline and cost cutting in resource allocation.

An important theme within NPM has been a macro level change to the form and functioning of public agencies. There have been shifts in organizational form; deregulation; privatisation; and downsizing. NPM has also caused changes in how the public bureaucracy is controlled, implying the creation of new regulatory and audit based organizations, with the intention of shaping the behavior of public sector professionals to ensure a uniform and high level of service quality (Ferlie, 2007; McLaughlin et al., 2002; Hood et al., 1999b).

1.3 The compatibility between NPM and risk management

The literature on complex organizations and accidents mainly consists of two schools of thought. One has an optimistic view of safety and is called High Reliability Theory (e.g. La Porte & Consolini, 1991, Weick et al., 1999; Roberts et al., 2005). It argues that safe operations are possible even in extremely hazardous technologies and organizations characterized by complexity, system dependencies, and tightly coupled interactions. The second school is the more pessimistic Normal Accident Theory (e.g. Perrow, 1984; Clarke, 1999), which argues that serious accidents in complex high technology systems are inevitable (Sagan, 1993). Hood and Jackson (1992) have related aspects of NPM to the Normal Accident Theory and worry that "*NPM could be a disaster waiting to happen"* (Hood & Jackson, 1992: 122). They argue that NPM increases the government's capacity to produce accidents for several reasons: growing urban density and population causes difficulties in effectively regulating hazardous processes; new technology of administration contributes to build interactive complexity and tight coupling into the public sector; the potential for misinformation within government has increased as a consequence of NPM due to its lack of a system view of the organization. Reasons for this increase in the government's capacity to produce accidents come from contextual changes and technological development. However, it has been demonstrated that NPM adds to these

factors some of the organizational ingredients for the production of accidents (Hood & Jackson, 1992). NPM's features of privatization, deregulation, and cost cutting seem particularly influential in counteracting safety and robustness, and cause a need to cope with the pressures to be faster, better and cheaper, potentially implying a compound pressure between efficiency and safety (Hood, 1991; Hood & Jackson, 1992; Reason, 1997; Rasmussen, 1997; Woods & Cook, 2004; Woods, 2006; Flin, 2006). In order for public sector organizations to maintain the capacity of robustness, detect risk signals, and learn from undesired events there is a need for a relatively high degree of slack (Hood, 1991; Marcus & Nichols, 1999; Cook & Rasmussen, 2005; Pettersen & Aase, 2007); a control framework focusing on input or process rather than on output; a personnel management structure that promotes cohesion without punishing unorthodox ideas; a task division structure that is organized for systemic thinking rather than on narrow compartmentalization; a responsibility structure that allow mistakes; and relatively loose couplings and emphasis on information as a collective asset within the organization (Hood, 1991; Allsop & Mulcahy, 1996; Walshe, 2003; Leape, 2005; Morath & Turnbull, 2005). In sum, the underlying values of NPM that put economy and production at center stage, may limit the capacity for public organizations to manage disruptions and variability, and thus operating safely (Hood, 1991; Woods, 2006; Flin; 2006)

1.4 Risk management in the public sector

Accidents and threats have always been present in society, but the increasing complexity and interconnectedness within society, including the public sector, contribute to the development of new types of risk and more complex causalities (e.g. Beck, 1997; West, 2000; OECD, 2003a, b; Aven et al., 2004; Wiig & Aase, 2007). The ability to understand the emergence of risk, and to manage and control risk is a prerequisite for individuals, organizations, and society to survive and operate safely (Aven et al., 2004, Institute of Medicine 2000; 2001). Over the past years the role of the state, as a regulator and risk manager, has increased (Majone, 1994; Hood et al., 1999a; 2001). There has been a major growth in academic discussions on the phenomenon of risk and regulation. Regulation of risk is not an attempt to eliminate risk; it is an attempt to manage risk (Hutter, 2001a). In this thesis risk management is defined in a broad sense as a process involving a range of activities for coping with risk, including how risk is identified and assessed, and how social interventions to deal with risk are monitored and evaluated (Hood & Jones, 1996). The management and control of risk within the state takes place at many system levels, ranging from policy level to street level bureaucrats by means of laws, rules, and instructions. Each system level can influence the others in an integrated and tightly coupled control system (Hovden &

Larsson, 1987; Rasmussen, 1997; Leveson; 2004). These system levels constitute subsystems within the state that offer different organizational interfaces or points of contacts between the organizational subsystem and its members (Büssing et al., 2000). Managing risk and preventing accidents within the public sector therefore depend on activities and interfaces among actors at different system levels (Hovden & Larsson, 1987; Rasmussen, 1997; Büssing et al., 2000; Leveson; 2004).

Most of the previous research on managing risk or breakdown in risk management has explored industrial settings and private business such as the Challenger Launch Decision (Vaughan, 1996), and the Exxon Valdez oil spill (Clarke, 1999). However, research covering the analogue processes of risk management and regulation within the public sector have been left rather unexplored (Hood et al., 1999b). This thesis draws attention to multilevel risk management processes in two public sectors: public healthcare and municipalities (local government sector). The risk management processes covered are those ensuring patient safety in the specialized healthcare sector and municipal emergency management in the municipal sector.

The thesis includes a multilevel exploration and analysis of how society establishes regimes to regulate and manage risk in the public sector (Hood et al., 1999b), by applying the socio-technical system perspective as a framework (Rasmussen, 1997; 2000). This approach includes the possibility of shifting levels of analysis within the socio-technical system involved in public risk management and gives rise to issues like regulatory regimes; tools and strategies applied in controlling and managing risk; understanding the emergence of and adaptation to, risks; information flow and learning processes among system levels of the socio-technical system; and characteristics of organizational interfaces among agencies and of national, regional, and local institutions that are important for public risk management processes (Baldwin & Cave, 1997; Rasmussen, 1997; 2000).

1.5 The research purpose

This thesis focuses on organizational interfaces in risk management processes in the public sector. The overall purpose of the study is to add to the knowledge of risk management processes in the public sector. More specifically, the following objectives have directed the research:

I. To improve knowledge of vital organizational interfaces in the socio-technical system involved in public risk management processes.
II. To improve knowledge about regulatory enforcement in public risk management processes.
III. To explore risk perception in different public risk regulation regimes.
IV. To explore information flow and learning processes among different system levels in public risk management processes.

1.6 The research problem

The overall research problem of the thesis is:

How can organizational interfaces across system levels explain risk management processes in the public sector?

The formulation of the research problem comes as a consequence of the perspective on risk management as a process involving a range of activities involving actors within different system levels of the public sector (Hood & Jones, 1996). There is a need to enhance the knowledge of the socio-technical system involved in risk management, in particular to understand the organizational interfaces among the system levels and their contribution to risk management processes in the public sector (Büssing et al., 2000; Rasmussen, 1997; Leveson et al., 2005).

I refer to the organizational interface concept as a point of contact among organizational subsystems and their members (Büssing et al., 2000) The use of the organizational interface concept among system levels is two-dimensional, referring both to a structural aspect in forms of the decomposed levels of the socio-technical system, and a process aspect in forms of the interaction across these levels (Rasmussen, 1997). The structural aspect is related to institutional design, administrative structures, and the legal framework defining responsibilities, and roles for different institutions at different hierarchical levels of the public sector. The process aspect is related to the interaction among the system levels in the public sector due to feedback mechanisms, formal and informal processes, communication, and activities

stated in the legal framework, or conflicts caused by diverging purposes, roles, tasks, and expectations among system levels.

1.7 Thesis limitations

In directing and narrowing the research process, the thesis makes the following limitations:

- There is a vast literature on the socio-technical system perspective (e.g. Geels, 2004; 2005; van Eijnatten, 1993; Ketchum & Trist, 1992), however this thesis is limited to the application of the socio-technical system perspective to risk management processes, as it is approached by Rasmussen (1997; 2000), Rasmussen & Svedung (2000), Svedung & Rasmussen, (2002), and further developed by Leveson, (2004) and Leveson et al., (2005; 2006).

- The exploration of public risk management processes could have emphasized topics such as power, trust, and regulatory standards setting. It could also have applied alternative theoretical perspectives implying other methodological approaches to the field, without emphasizing a multilevel approach, by exploring public risk management processes within single system levels in more detail. However, this thesis is an empirical exploration of public risk management in a multilevel perspective, one that is almost absent in current research. There is a need to provide new insight, understanding, and improvement of the risk management processes, as they appear in real context in the public sector.

- Further thesis limitations are presented in the following chapters in which they belong.

1.8 The structure of the thesis

This thesis consists of two parts. Part I describes the background, research problem, and the research process, including the theoretical and methodological perspectives and their rationales. Part I summarizes the results of the four research articles, and describes the relationship among them. Part I discusses answers to the research problem and associated research questions, the implications for risk management in the public sector, and suggests directions for further research.

Part II contains the four research articles included in the thesis. The articles, along with their publication information are listed below:

I: Wiig S. & Aase, K. (2007). Fallible humans in infallible systems? Learning from errors in health care. *Safety Science Monitor,* (Fall 2007, Forthcoming).

II: Wiig, S. (2007). Risk regulation strategies in public emergency management – A learning perspective. *International Journal of Emergency Management*, Vol. 4, No. 4, pp. 584-599.

III: Wiig, S. & Lindøe, P.H. (2007a). Patient safety in the interface between hospital and risk regulator. In Aven, T. & Vinnem, J.E. (eds.) *Risk, Reliability, and Societal Safety*, Vol. 1, pp. 219-227. London, Taylor & Francis.

IV: Wiig, S. & Lindøe, P.H. (2007b). Risk perception within different risk regulation regimes. In review for *Policy and Practice in Health and Safety.*

2 Theory

This chapter presents the general theoretical contributions of the thesis, addressing the research problem: *How can organizational interfaces across system levels explain risk management processes in the public sector?*

The research problem is broad but comprehensive. In order to demonstrate important theoretical aspects of relevance for the research problem and demonstrate their relationship, the risk governance concept (Renn, 2005) is used to direct the more specific theoretical topics of interest. A set of more specific theoretical contributions is used to operationalize the research problem by developing research questions that have guided the research process. For a more thorough presentation and discussion of applied theoretical contributions I refer to each of the research articles in Part II.

2.1 Risk governance

In the last decade, the term "governance" has gained in popularity in the literature on international relations, comparative political science, policy studies, sociology of environment, and in risk research (e.g. Renn, 2005; Braithwaite et al., 2007; Hutter & Jones, 2007). Governing choices in modern societies is an interplay among governmental institutions, economic forces and civil society actors (Renn, 2005; Knodt, 2004). It is useful to distinguish horizontal from vertical governance (Benz & Eberlain, 1999). The horizontal level concerns the relevant participants in decision-making process within a geographic region or a functional segment. The vertical level concerns the links among these segments, such as the institutional relationship among municipalities, regional, and state level (Renn, 2005, Benz & Emberlain, 1999).

Risk has become an increasing interest for governance (Rothstein et al., 2006). The concept of risk governance integrates a broad view of risk, one that encompasses risk management and risk analysis, and moreover examines how risk-related decision-making unfolds when a variety of actors are involved in the processes, requires coordination, and understanding of a large number of roles, perspectives, goals, and activities. According to Renn (2005) the concept of risk governance builds on the observation that collective decisions about risk are the result of a "mosaic" of interactions among governmental or administrative actors, science communities, corporate actors, and actors in civil society. The interplay among these actors has different dimensions, including public participation, stakeholder involvement, and the formal horizontal and vertical structures in which it occurs. The problem solving capabilities of the actors are limited and often not satisfying for the

challenges facing today's society. Risks in society require coordinated efforts amongst numerous actors some times beyond the borders of countries, sectors, hierarchical levels, disciplines, and risk fields. Risk governance moreover illuminates the contextual aspect of risk, by including aspects such as historical and legal framework, governance structure, risk perception, regulatory regimes, regulatory style, and organizational capacity involving intellectual and material assets (Renn, 2005; 2007).

When looking at risk governance structures it is impossible to include all variables that may influence risk decision-making processes (Renn, 2005). Renn (2005) recommends limiting the effort to the factors and actors in which theoretical reasoning and/or empirical analysis are demonstrated to be important in the outcome of risk governance. In this thesis I have delimited the governance structure aspects by using the socio-technical system perspective (Rasmussen, 1997; 2000) as a framework to map actors and vital organizational interfaces involved in the two segments in the public sector and to understand vertical risk governance processes and information flow within the two regimes. Moreover, the broad integrative perspective of the risk governance approach makes a variety of theoretical contributions possible, making it necessary to define the theoretical perspectives. My perspectives cover risk regulation regimes (e.g. Hood et al., 1999a; 2001); strategies to control risk (e.g. Baldwin & Cave, 1999; Ayres & Braithwaite, 1992; Hawkins & Thomas, 1984); learning in organizational interfaces (e.g. Argyris & Schön, 1996; Reason, 1997; Allsop & Mulcahy, 1996; Gherardi & Nicholini, 2000); and risk perception in risk regulation regimes (e.g. Pidgeon, 2003; Pidgeon et al., 1992; Kasperson, 1992; Kasperson et al., 1988).

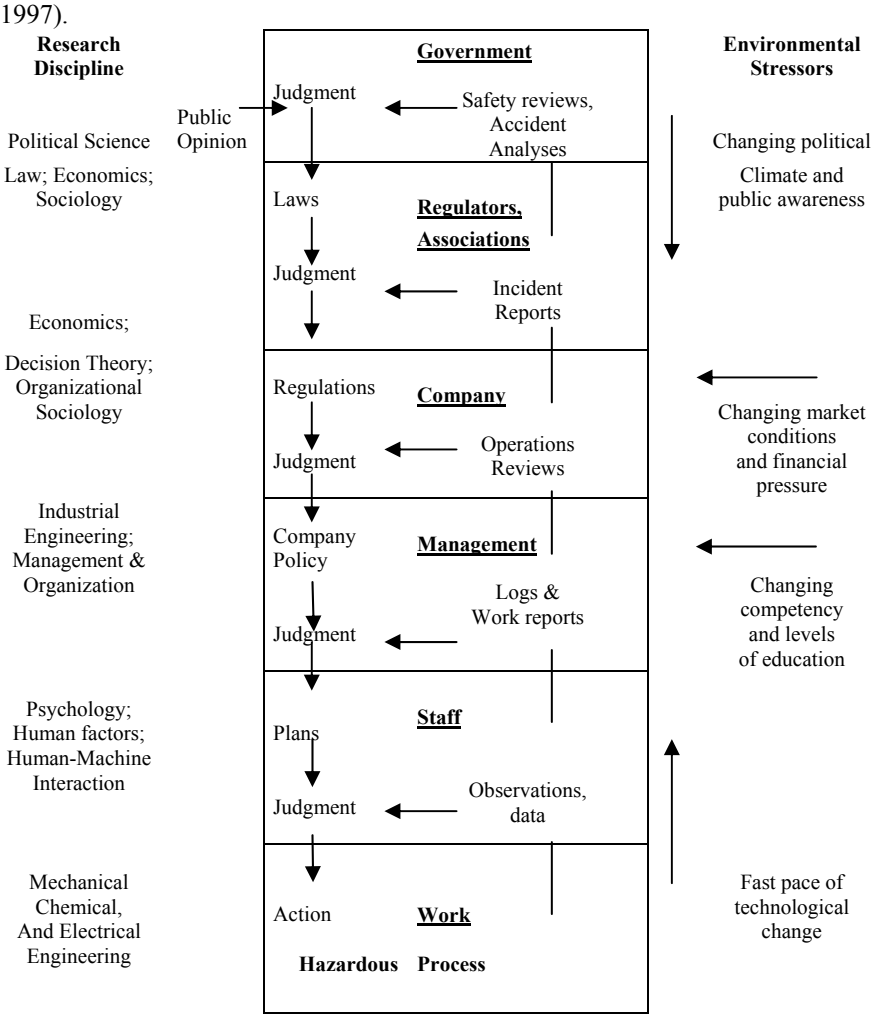
2.2 Risk management in a socio-technical system perspective

The thesis applies a socio-technical system perspective in order to examine the phenomenon of risk management processes across organizational interfaces (Rasmussen, 1997; 2000; Rasmussen & Svedung, 2000; Leveson, 2004; Leveson et al., 2005; 2006). Managing risk involves numbers of actors and stakeholders at different levels of society. The dynamics of change and the interaction among these levels of society are important for developing sound risk management processes (Svedung & Rasmussen, 2002). Traditionally, the system levels are studied separately, and few attempts are made to explore the effects of dynamic interaction across system levels (Rasmussen, 1997; 2000; Rasmussen & Svedung, 2000; Svedung & Rasmussen, 2002; Kirwan, 2001). Thus, there is a need for a system perspective and multilevel studies to concentrate on the vertical interaction across all system levels representing the control structure involved in risk management within the society (Rasmussen, 1997). In the socio-technical

system perspective the system is viewed as hierarchical structures, where each level imposes constraints on the activity of the level beneath. Control processes operate in the organizational interfaces among these levels, and effective communication channels among the levels are needed to send information upwards and downwards. Feedback is critical for the system to provide adaptive control, and a key issue is to analyze the system holistically and evaluate the organizational interfaces among the system components and determine the impact of component interactions (Leveson, 2004; Rasmussen, 1997). The socio-technical system is viewed as a dynamic system involving continuous processes adapting to achieve its ends and to react to changes in itself and its environment (Leveson et al., 2006). Accidents are viewed as the result of flawed interactions among humans; societal and organizational structures; engineering activities; and physical system components. The process leading up an accident can be described in terms of adaptive feedback functions that fail to maintain safety, as system performance is dynamic and changes to meet several set of goals and values over time (Leveson et al., 2005).

The different levels of risk management processes and the framework conditions constitute the socio-technical risk management system within the public sector, involving the system levels: government, regulators and associations, company, management, staff, and work operation (Figure 1) (Rasmussen, 1997). At each system level, changes or environmental stressors may be introduced, including new legislation, a changing political climate, changing market conditions (e.g. changes imposed by NPM), changes in company competency levels, and technological changes. Given the interconnectedness among levels, such changes will affect the entire system (Rasmussen, 1997; 2000; Rasmussen & Svedung, 2000).

Figure 1. The socio-technical system involved in risk management (Rasmussen, 1997).



Some of the key challenges for risk management processes in socio-technical systems are the following: (1) information flow, including communication channels and feedback processes, among decision makers at all levels of the system; (2) the nature of risk and its characteristics are comprehensive and diverse perceptions of risk exist within different system levels; (3) several activities may take place in parallel, decisions about risk are made out of diverse rationalities, and it is difficult for employees, decision-makers, regulators, and politicians to understand the extended effect of their individual actions and decision within the system (Rasmussen, 1997; Leveson, 2004). Accidents may develop over years in a process where signals and precursors

are misperceived because of cultural norms and beliefs; regulatory shortcomings (e.g. Kennedy, 2001) or events occurring unnoticed or misunderstood and not managed within the system (Turner & Pidgeon, 1997; Rosness et al., 2004, Hopkins, 2007). The occurrence of "modern" accidents represents the visible manifestation of the limited ability to control risk (Kirwan et al., 2002; Perrow, 1984).

The socio-technical system approach advocated by Rasmussen (1997; 2000), Rasmussen and Svedung (2000), and refined by Leveson (2004) has been applied for the purposes of accident modelling and analysis. In that sense the models have been assumed to be normative or prescriptive, implying that the system should fit prescribed indicators at each level in order to perform as expected, and avoid accidents (Le Coze, 2007). In this thesis the socio-technical system perspective is used for explorative and descriptive purposes. It depicts and describes risk management processes from a multilevel perspective (Baram & Hale, 1998), categorizing the involved system levels, and the organizational interfaces between these system levels. The socio-technical perspective has also been used to structure data collection and analysis.

2.3 Risk regulation regimes

Regulation is a topic that has stimulated interest in economics, political science, sociology, history, psychology, and other disciplines (Baldwin & Cave, 1999). The concept of regulation has been defined in numerous ways (e.g. Baldwin & Cave, 1999; Hood et al., 1999a; 2001; Black, 2002; Walshe, 2003). Broadly it denotes the use of public authority (often in the hands of public agencies) to set and apply rules and standards. The concept of regulation is usually directed towards institutions outside the public sector, and we are not accustomed to think of the government as regulating itself. Since this thesis explores regulation within the public sector, it is necessary to clarify what is meant by regulation inside government. According to Hood et al. (1998; 1999b; 2000) three features characterize regulation inside government: (1) one bureaucracy shapes the activities of another, (e.g. the Norwegian parliament expects the municipalities to perform risk and vulnerability analysis); (2) there is some degree of organizational separation between the regulating bureaucracy and the regulatee, (e.g. the County Governor is the regulator established at the regional level to inspect municipalities at the local level); and (3) the regulator has some kind of official mandate to scrutinize and change the behavior of the regulatee (e.g. the regulator can interfere in cases of non-compliance in order to change the municipal behavior).

Regulation can be viewed as centrally concerned with the control of risk (Baldwin & Cave, 1999; Kirwan et al., 2002), and different regulatory regimes are developed to respond to risk and influence the risk management practices in organizations (Hutter & Jones, 2007; Hood et al., 1999a; 2001). The objective is to get organizations to give risk management practices priority over other organizational objectives (Ayres & Braithwaite, 1992; Hutter & Jones, 2007). The concept of risk regulation regime is abstract and refers to the way the state regulates risk in a particular domain. It denotes the complex of institutions, practices, and ideas that characterize the state's management of each risk. Risk regulation regimes have several dimensions and their emphasis vary according to the perspective and analytic interests of the observer (Hood et al., 1999a; 2001; Majone, 2002). In this thesis the concept is applied according to Hood et al. (1999a; 2001). Their cybernetic framework organizes and links categories with other features of regulation. Regulation is seen in its most abstract meaning as a control system, and the risk regulation regime in a general sense constitutes the combination of three control components that any control system contains: standard setting (means by which goals are set), information-gathering (means by which the state of the system is observed and monitored), and behavior modification (means by which power or influences are imposed on the system to change its state). These components align with policy-making, monitoring, and enforcement. Different regimes vary according to these components and there might be constancy or flexibility of relationship among these components when different risks are being regulated (Hood et al., 1999a, 2001; Baldwin et al., 2000; Baldwin & Cave, 1999; Black, 2002; Walshe, 2003). Risk regulation regimes cannot be understood without going into the contextual aspects of the regime (Walshe, 2003; Hood et al., 1999a; 2001; Renn, 2005; Baldwin, et al., 2000; Baldwin & Cave, 1999). Contextual aspects are the backdrop of regulation, such as the kind of risks being addressed and the way in which risk perception varies among social groups; the actors producing or being affected by the risk, how are they organized, and what public preferences and attitudes are related to the risk. Moreover, the content of regimes is important to understand when exploring differences among regimes. Regime content consists of regulatory objectives and the amount of regulation brought to bear on any risk in a regime; the organizing of the regulatory responsibility and structure of institutional arrangements; operating styles of the regulators; and the formal and informal processes through which regulation is enforced. The context and content of risk regulation regimes could have been examined in other ways (e.g. Walshe, 2003), however these elements have received the most emphasis in the risk regulation literature (Hood et al., 1999a; 2001, Walshe, 2003).

In order to analyze different risk regulation regimes, Hood et al. (2001) have developed an analytical framework denoted the Risk Regulation Regime (RRR) comprising a two-dimensional anatomy of a regime constituted by the control components on the one side (standard setting, information collection, and behavior modification) and on the other side: contextual aspects (type of risk, public preferences and attitudes, and organized interests), and content aspects (size, structure, and style). I have applied the RRR framework (Hood et al., 1999a; 2001) to analyze the two studied public sector risk regulation regimes according to how officials and employees perceive risk, and how risk is a subject for amplification and attenuation within these risk governance structures and processes (Pidgeon et al., 2003; Rothstein, 2003a; Pollak, 1996).

2.3.1 The control of risk

How regulators approach their role and function appears to be culturally dependent. Similar regulatory challenges result in different regulatory solutions in different regimes and different nations. The way regulators conceive their mission and their regulatees is important in explaining the approaches of different regimes (Walshe, 2003; Rothstein, 2003a; Hawkins & Thomas, 1984; Ayres & Braithwaite, 1992). A vital aspect in understanding risk regulation processes is to study regulatory enforcement practices. Just as it is important to know how standards are formed, it is also important to gain knowledge about how these are transmitted downward the regime levels or sub-systems, and implemented at the street level. The complexity of regulatory regimes, the complexity of problems in the area to be regulated, and the distance between regulatory authority and the regulated, all make the issue of how to control the discretion at the street level crucial (Hawkins & Thomas, 1984; Rasmussen, 1997).

It is difficult for risk regulators to choose the appropriate enforcement strategies to target the optimal method of regulating risks. Regulators seek to enforce compliance with the law, not merely through formal enforcement and prosecution, but also through a host of informal techniques, including education, advice, persuasion, and negotiation (Baldwin & Cave, 1999). According to Kagan and Scholz (1984), problems of regulatory enforcement usually refer to the motives, attitudes, and capabilities of the regulatee. Three "images" of the regulatee are created in the literature with corresponding theories to explain non-compliance. The first image depicts the regulatee as *amoral calculator*, motivated entirely by profit. This regulatee disobeys the law if it is beneficial to do so, and non-compliance stems from economic calculation. The second image depicts the regulatee as a *political citizen*, tending to comply with the law, partly because of a belief in the law, and

partly because of long-term interest. In this case, non-compliance stems from principled disagreements with regulations that are sometimes regarded as arbitrary or unreasonable. The third image depicts the regulatee as *organizationally incompetent*, whose intentions are to obey the law, however it is potentially fallible due to lack of organizational capacity to do so. In this case the non-compliance arises from organizational failure. Each of these images requires different regulatory enforcement strategies (Kagan & Scholz, 1984; Reiss, 1984; Ayres & Braithwaite, 1992; Walshe, 2003) and roles for the regulators (Reason, 1997; Reiman & Norros, 2002). To deal with the amoral calculators the regulatory authority should emphasize aggressive inspection. The goal is deterrence and the inspectors appear as policemen. To deal with the political citizen the regulatory authority should act as a politician, persuading the regulated of the rationality of the case. In order to deal with the organizationally incompetent entity the regulator should serve as a consultant, bridging the competence gap through education. Each of these theories of corporate legal behavior or misbehavior, capture important aspects of reality. However, the diverse sources of non-compliance imply that reliance on any single theory of non-compliance is likely to be wrong, and, when translated into enforcement strategies, counteractive. This means that regulators need to be adaptive and should be aware that non-compliance may have multiple reasons. Regulatory inspectors must be prepared to shift roles according to their analysis of the regulated organization (Reiman & Norros, 2002; Kagan & Scholz, 1984; Reiss, 1984; Ayres & Braithwaite, 1992).

Diverse strategies in enforcing regulation described in the literature usually concern the use of compliance versus deterrence approaches as strategies for applying legal standards (Walshe, 2003; Baldwin & Cave, 1999; Hutter & Lloyd-Bostock, 1992; Ayres & Braithwaite, 1992; Reiss, 1984). Compliance is an informal style of regulation emphasizing diplomacy, persuasion, and education rather than the routine application of sanctions to produce a compliance culture within the regulatee. The regime promoting compliance approaches is flexible and tolerant, and its regulators use discretion and pragmatism in their application of the law. The goal is to achieve compliance without invoking the formal legal process. In contrast, deterrence relies on penalties or punishment to discourage the regulated from breaking the rules (Hood et al., 2001; Baldwin & Cave, 1999; Braithwaite et al., 1987). A regime promoting deterrence approaches is excessively legalistic, involving a strict imposition of standards. Proponents of deterrence approaches tend to argue that compliance approaches imply relationships between regulators and regulatees through shared experiences, contacts, and staff exchanges or familiarity, making routine prosecution unthinkable. Conversely, proponents of compliance approaches argue the deterrence approaches fail to improve

regulatee performance, and instead causes resentment, hostility, and a lack of cooperation in those regulated (Baldwin & Cave, 1999).

However, some researchers argue for a hybrid approach, referred to as responsive regulation. This approach promotes compliance responses for those regulatees who have been identified as poorly informed or morally concerned about the regulatory requirement, while deterrence responses are promoted for regulatees who show themselves to be opportunistic and amoral (Ayres & Braithwaite, 1992). Responsive regulation is pragmatic and replaces the choice between compliance or deterrence approaches with a highly flexible, situationally specific, and adaptable approach. It avoids the "one size fits all" approach in favor of contingency – making the nature of the regulatory regime highly dependent on the behavior of the individual regulated organizations. Moreover, this approach makes use of a hierarchy of regulatory strategies and sanctions in each of the three control components of standard setting, information collection, and behavior modification (Walshe, 2003). This is often presented as a set of pyramids - one pyramid of regulatory enforcement strategies corresponding to a second pyramid of regulatory sanctions. The aim is to provide the regulator with a full range of regulatory interventions that can be applied responsively and tailored to the needs and behavior of each of the regulated organizations. The two other key words: tripartism and empowerment, are important for responsive regulation. Advocates of responsive regulation argue for tripartism, meaning that the regulatory process should be designed to include and cooperate with stakeholders beyond the regulator and the regulated for the purpose of regulation (e.g. by using the stakeholders as informants and secure greater regulatory compliance by taking advantage of the stakeholders to pressure the regulated organizations). According to the idea of empowerment, regulation should enable the regulated organizations to perform well rather than impose requirements that may constrain or limit their performance. Thus, regulation should promote improvement beyond the short-term adjustments, and emphasize long-term goal of improvement around regulatory objectives. In sum, proponents of responsive regulation argue that the trick of successful regulation is to establish a synergy between punishment and persuasion (Baldwin & Cave, 1999; Ayres & Braithwaite, 1992; Walshe, 2003)

2.3.2 Learning in organizational interfaces

The regulatory process can be part of a wider learning cycle of legislators, regulators, and the regulated organizations. The sharing of information among agencies, including regulatory authorities, is essential aspect to improving risk management (e.g. Reason, 1997; Allsop & Mulcahy, 1996; Hood et al., 1999a; 2001; Walshe, 2003; Price, 2002; Allsop & Sakes, 2002). The focus is

on the systemic improvements generated from local indicators such as non-compliance or deviation from safe work practice and how these are caused by regulatory, organizational, and managerial conditions. To improve risk management, preventive measures, and organizational changes based on such indicators should be introduced to eliminate the problems. These improvements should represent new safety standards and be incorporated into legislation, which in turn would change the regulator's inspections and surveillance criteria in an ongoing process (Reason, 1997). This learning cycle (Reason, 1997; Allsop & Mulcahy, 1996; Walshe, 2003) involves information exchange and learning in the organizational interfaces involved in risk governance (Renn, 2005; Rasmussen, 1997; 2000; Reason, 1997). Similar to the learning cycle perspective is the view of risk regulation as a problem solving process involving activities such as: (1) discover risk and define problem; (2) make and promulgate rules for control at one level within a regime (legislating); (3) assess conformity to rules (monitor); (4) apprise results and take action (enforcing); (5) monitor effects of action and learn (evaluation) (Kirwan et al., 2002). Both perspectives promote underlying values of regulation as a continuous learning process, which in practice implies that learning is a collective capacity that produces organizational and inter-organizational risk management practices (Gherardi & Nicolini, 2000; Weick et al., 1999; Rosness, 2002; Dekker et al., 2007; Dekker, 2007). Given the complexity of the explored regimes in this thesis, producing this collective capacity entails processes across different system levels and occupational groups, requiring a multilevel exploration in order to address aspects promoting or counteracting these learning processes (Catio et al., 2005; Büssing et al., 2000).

Viewing risk regulation as a learning process poses a dilemma for the regulator-regulatee interface (Wilpert, 2006; Baram, 1997). The issue of how to manage and learn from undesired events in the relationship between regulators and regulatees is sensitive and can be drawn between the liability aspect and the need for openness to obtain important information (Wilpert, 2006). Regulators face difficulties in accomplishing the dual mission of regulatory enforcement and learning (Tamuz, 2001). Formal activities and enforcing regulation may interfere with learning activities since the incentives designed for regulatory enforcement affect the collection and interpretation of knowledge (Wilpert, 2006; Tamuz, 2001). According to Tamuz (2001) there is a need for research on how regulatory authorities carry out this dual mission in order to create a healthy learning environment. This aspect has attracted only limited attention in the literature, and therefore this thesis analyzes the mode of regulatory enforcement strategies from a learning perspective (e.g. Aase & Nybø, 2004; Hansen et al., 1999; Tamuz, 2001; Tucker et al., 2001; Tucker & Edmondson, 2003). It analyzes activities related to deterrence and

compliance strategies, with regard to their potential to promote or constrain the learning processes of the regulatees (Baram, 1997).

2.4 Risk perception in risk regulation regimes

Very few risks are perceived and experienced similarly across constitutive groups and sub-systems within organizations and society. It is more likely that there is a variance, which has implications for risk identification, risk management, and learning from risk events (Hutter, 2005, Hutter & Power, 2005; Krimsky & Golding, 1992). The previous subchapters have demonstrated that risk regulation regimes are complex systems comprising multiple subsystems which are themselves subject to different pressures and which have their own sub-cultures (Rothstein, 2003a, Hood et al., 2001). As a consequence, officials and employees in different subsystems of the regimes may have divergent perception of and attitudes towards risks and their regulation (Rothstein, 2003a, Hutter & Lloyd-Bostock, 1992; Hutter, 2001a). Such divergences may result in policy being implemented in unintended ways if the officials monitoring and enforcing regulation perceive the magnitude and the need for controlling certain risks in ways that policy makers do not (Rothstein, 2003a; Rasmussen, 1997). Scant attention has been paid to the factors shaping regulatory officials' risk perception and their attitudes towards the regulation of those risks (Rothstein, 2003a); more attention should be paid to the role of organizations and institutions in social amplification and attenuation of risk in order to understand how risk signals may be denied, de-emphasized, overemphasized, or misinterpreted (Hutter & Power, 2005; Kasperson et al., 2003; Freudenburg, 2003; Pidgeon et al., 2003).

Risk perception is based on how information on the risk source is communicated, the psychological mechanisms for processing uncertainty, and previous experiences of danger. People construct their own reality and assess risks according to their subjective perceptions (Renn, 2004; 1992). Various models have been developed to represent the relationship among perceptions, behaviors, and qualitative characteristics of risk. Within the psychometric paradigm (e.g. Slovic, 2000; Slovic et al., 2000) research demonstrates that perceived risk is affected by characteristics such as voluntariness, lack of control, dread, catastrophic potential, fatal consequences, and inequitable distribution of risk and benefits; it is also affected by whether or not hazards are unobservable, unknown, new, or delayed in their manifestation of damage. Risk perception research rooted in the psychometric paradigm can offer insights into the individual's processing of hazard information (Slovic, 2000; Pidgeon et al., 1992).

In a broader sense, the cognitive heuristics and biases that shape individuals' risk perceptions are themselves shaped by organizational and institutional contexts, processes, and decisions. In terms of risk regulation, rules and regulations are powerful, and unavoidable, imposing structure and procedure on a wide variety of organizational forms while stimulating the strategic interactions of organizations. Strategic interaction occurs among regulators, managers, and employees; thus, the understanding of risk is drawn in different directions (Jaeger et al., 2001). In order to see the broad picture of risk perception, to understand influencing factors on risk perception across organizational interfaces, and to assess contextual implications on risk perception, the social amplification of risk framework (SARF) has been applied in this thesis (e.g. Pidgeon et al., 2003; Kasperson, 1992; Kasperson et al., 1988). In brief, the SARF is an integrative framework serving to describe the dynamic social processes underlying risk perception and response (Kasperson et al., 2003). It is founded on the belief that hazards interact with psychological, social, institutional, and cultural processes in ways that may increase or decrease the perception of risk and shape risk behavior. The experience of risk is not just an experience of physical harm; it is also the result of a process by which individuals or groups learn to acquire or interpret hazards (Kasperson et al., 1988; Kasperson, 1992; Renn, 2003). Hazardous events hold a signal value, which individuals and social groups may perceive differently. These signals are subject to transformations as they are filtered through individual and social amplification stations (e.g. mass media, groups of scientists, governmental agencies, and politicians). Social amplification may have repercussions far beyond the initial impact of the event, bringing effects such as demands for regulatory constraints, litigation, or loss of credibility and trust. These processes imply that diverse hazards are given more or less attention due to the diverse understanding of signals among individuals and groups, causing an amplification or attenuation of risks. This thesis argues in favor of the need to link risk amplification and attenuation to the role of organizations and institutions in the social processing of risk. Since several contemporary risks originate in socio-technical systems, risk management and regulatory processes governing the institutional behavior, are key parts of a broader amplification process (Pidgeon et al., 2003; Kasperson et al., 2003).

2.5 Research questions

The theoretical contributions presented in this chapter indicate that the study of risk management processes in the public sector is a promising and challenging area of research. This chapter has demonstrated a need for knowledge about how humans at different levels of a socio-technical system perceive risk, as an aspect of public risk management processes. Moreover,

managing risk requires feedback and feed forward processes across organizational interfaces in order to learn from undesired events and improve public risk management processes. The theory has also revealed that regulatory enforcement is a vital aspect, because it constitutes a control mechanism enforced by the state to ensure high quality of public risk management processes.

In light of my research purpose and problem (Paragraphs 1.5 and 1.6), the theoretical framework becomes the basis of four research questions:

1. *How can a socio-technical system approach explain important organizational interfaces in public risk management processes?*

2. *How do different risk regulation regimes shape risk perception among officials and employees within the regimes?*

3. *How can the interface between risk regulator and regulatee affect risk management processes?*

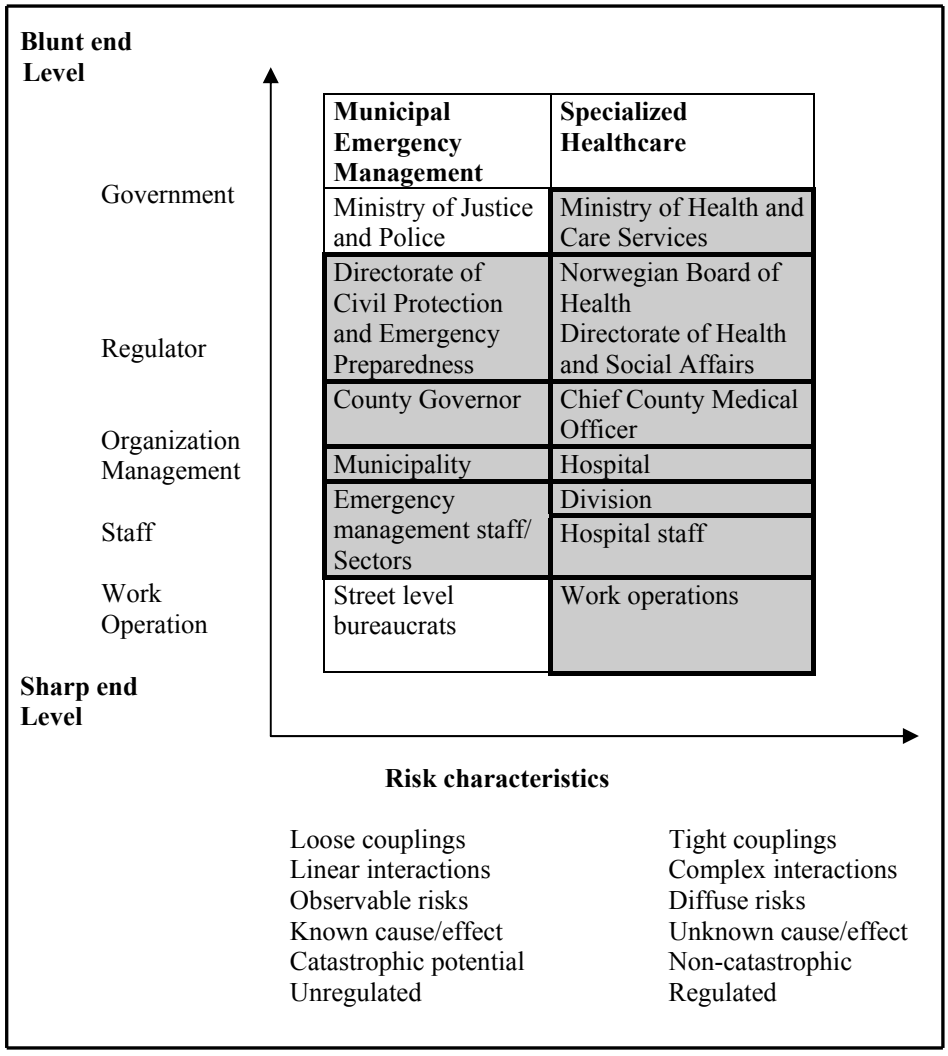
4. *How can regulatory enforcement strategies influence information exchange and learning processes within the regulated?*

2.6 Thesis working model

In previous subparagraphs (2.1-2.4), the theoretical contributions of the thesis are elaborated, and the research questions are presented (2.5). In order to demonstrate the use of the theoretical contributions and to demonstrate how the thesis answers the research questions in an empirical multilevel case study, I have developed a thesis working model (Figure 2).

The working model depicts the socio-technical systems involved in risk management (Rasmussen, 1997; 2000) in municipal emergency management and specialized healthcare. In the model system levels are described according to a blunt end - sharp end dimension (Rosness et al., 2004; Hollnagel, 2004; Reason, 1997). The organizational interfaces (Büssing et al., 2000) explored in the thesis exist across these system levels. The system levels covered in the thesis within each sector are highlighted in grey. The working model depicts the risk regulation regimes according to a risk characteristics dimension (Slovic et al., 2000; Slovic, 2000). The risk characteristics serve to explain why the public sector needs to develop different risk regulation regimes (Hood et al., 1999a; 2001).

Figure 2. Thesis working model



3 Methodology

In this chapter I describe my the philosophy of science positioning, research strategy, research design, data collection, data analysis, and how I establish trustworthiness in the research process. Furthermore, I reflect on the methodological advantages and disadvantages of conducting a multiple embedded case study of risk management in the public sector.

3.1 Philosophy of science positioning

There exist numerous perspectives on risk management, depending on underlying risk perspectives (Jones & Hood, 1996; Renn, 1992), ranging from a positivist to a constructivist perspective on the edges of a continuum. The positivist view conceives risk as a physically given attribute of hazardous technologies where objective facts can be explained, predicted, and controlled by science and be separated from subjective values. In the constructivist perspective, risk is a socially constructed phenomenon, rather than a physical entity that exists independently of the humans who assess and experience its effects. In this perspective, decisions are never value-free (Renn, 1992; Shrader-Frechette, 1991; Bradbury, 1989). Shrader-Frechette (1991) refers to these two philosophical positions as *naive positivist* and *cultural relativist*, and argues that they both fail, in part because they are reductionistic, and that there is a need for a middle position denoted *scientific proceduralism*. Naive positivists reduce risk evaluation to be value-free, independent of methodological value judgements; while the cultural relativists reduce risk to a collective construct and overemphasize the value judgements. I agree with Shrader-Frechette (1991), and contend that societal risk evaluation is neither wholly objective nor merely a construct. Constructs do not kill people – faulty reactors, improperly stored toxics, and poor risk evaluation do. At least some hazards are real and measurable. As a consequence there is a need for a middle position, *scientific proceduralism,* founded on a rationale in which the ability of societal risk evaluations to withstand criticism by both scientists and lay people affected by hazards; the ability of risk evaluations to change, as new facts and information are discovered; and the ability of risk evaluations to explain and predict both risks and the human responses to them (Shrader-Frechette, 1991).

Kasperson (1992) offers a synthetic view of risk: "*as in part an objective threat of harm to people and in part a product of culture and social experience. Hence, hazardous events are "real": they involve transformation of physical environment or human health as a result of continuous or sudden (accidental) releases of energy, matter, or information or involve perturbations in social and value structures*" (Kasperson, 1992: p. 158). In

other words, this view expresses the idea that risk comprises both an ontological and an epistemological domain. As an objective threat or harm to people, risk enjoys an ontological realism. As an element of the world subject to interpretation, filtered by social and cultural factors, risk enjoys an epistemological domain. Eugene Rosa uses the synthetic view to offer a corresponding definition of risk, used in this thesis, as a situation or an event where something of human value (including humans themselves) is at stake and where the outcome is uncertain (Rosa, 1998; 2003). How humans according to this perspective select issues of concern and how they model likelihood within a risk regulation regime may indeed be a result of cultural conventions and social constructions within the regimes. However, the threat of being affected by these consequences is real in the sense that humans might suffer or die once the risk manifests itself in an accident or release of hazardous material (Renn, 1998).

Relating the philosophical considerations to societal safety, which is the scientific tradition this thesis is conducted within, it is a new research area that applies theories and methodological framework from established research traditions such as sociology, psychology, economy, technology, and political science (Kruke et al., 2007; Kjærland, 2007; Nilsen, 2007). The societal safety tradition in general, and this study in particular, argue for a multidisciplinary approach to risk management. Since this study incorporates several aspects of risk management, there is a need for an eclectic application of scientific contributions regarding research on risk perception, organizational learning, and regulatory enforcement to provide insight to the field and a theoretical framework for the thesis. Consequently, the study applies diverse theoretical perspectives and theoretical contributions, and takes advantage of previous research in fields such as sociology, psychology, medicine, and anthropology. Hence the study cannot be strictly theoretically positioned. However, the study emphasizes contributions inspired by social construction, but not in an absolute manner. As an example, I argue for a practice-based perspective that views safety as a social construct that depends on collective processes. Nevertheless, the risks whether they are perceived as, and acquired knowledge from collective processes or not, in some way involve physical harm to people, meaning there is ontological realism. However, the elements of the world in which people interpret and create safety from are socially constructed. The example shows that my philosophy of science positioning is consistent with Kasperson's (1992) argument for a synthetic conceptualization of risk.

A synthetic view is also methodologically desirable. Because ontological realism presupposes that the world exists independent of percipient actors and their social construction of it, there is a world in which research about

phenomena can be conducted and in which the results will have potential impact.

3.2 Research strategy

In order to explore organizational interfaces and processes, a qualitative research strategy was chosen to provide insight into organizational matters, risk management processes, and discourses in different public risk regulation regimes (Benson-Rea & Myers, 2006). The main research strategy is a case study approach (Ragin & Becker, 1992; Yin, 1999; 2003; 2004). The case study can provide descriptions, and test, generate and refine theory, models or concepts (Eisenhardt, 2002; Vaughan, 1992).

There are diverse perspectives with regard to the meaning of "case" and "case study" (e.g. Gerring, 2004; Ragin, 1992, Stake; 1994). Ragin (1992) applies two key dichotomies to explain how cases are conceived: 1) whether cases involve empirical units or theoretical constructs, and 2) whether these are understood as general or specific. In this study, cases are conceived as empirical units existing prior to the study, not as theoretical constructs developed in the course of the research process. In the overlap of philosophy and methodology, this perspective places the study in a realist perspective, viewing cases as objects. Proponents of cases as empirically real (e.g. Vaughan, 1992) often view cases as instrumental (Ragin, 1992), meaning that cases are examined to provide insight into an issue or to refine theory, and the case itself is of secondary interest (Stake, 1994). In this study, regulated organizations along with the regulatory authority, defined as the cases, are not of primary interest, but they are scrutinized to understand public risk management processes.

A case study is not a method but a research strategy (Hartley, 2004; Yin, 1999; 2003). According to Yin (2003) a case study can be conceived as an empirical research investigation of a contemporary phenomenon, within its real life context, especially when the boundaries between the phenomenon and the context, are not evident. The strategy is preferable when exploring a complex phenomenon, and enables the researcher who deliberately wants to cover contextual conditions to incorporate them in a holistic manner (Yin, 2003; 1999; Ragin, 1999). This study covers ongoing risk management processes in socio-technical systems, implying that processes are complex and interconnected involving multiple organizational interfaces among system levels; and are influenced by contextual conditions such as public interests, political and financial pressure, technological development, and changes in marked conditions (Geels, 2005; Rasmussen, 1997), that are beyond the researcher's control. Consequently, there is a need for a flexible research

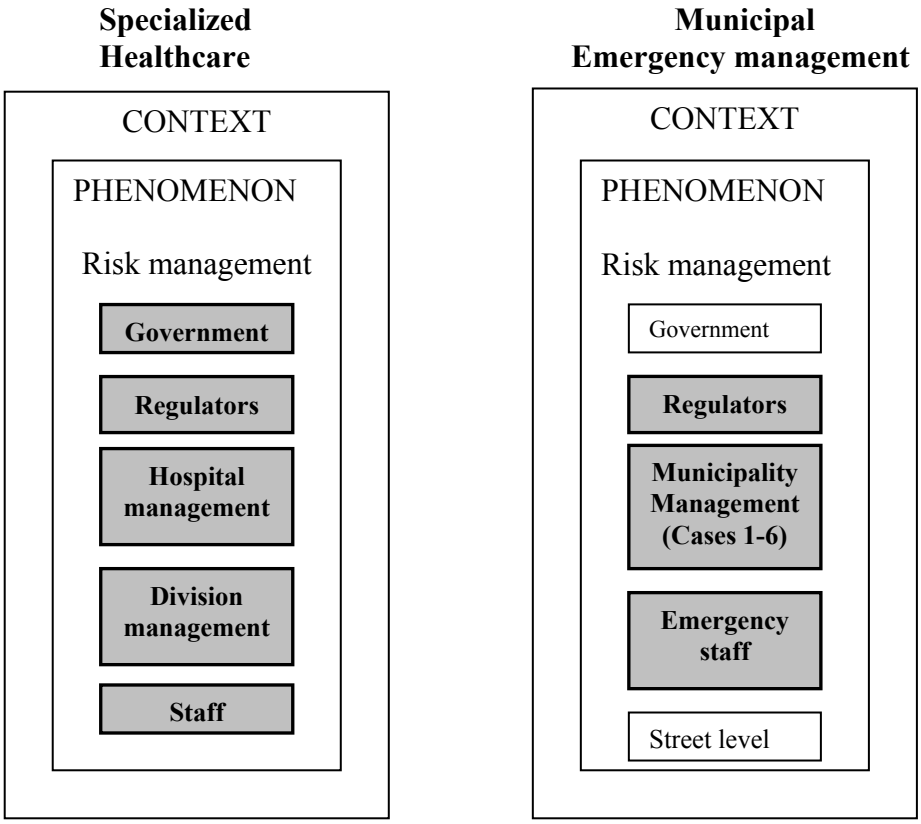
strategy and multiple methods to capture the phenomenon holistically, in order to understand how behavior and social processes occur and are influenced by contextual conditions (Hartley, 2004; Yin, 1999). Moreover, the case study approach is particularly applicable in this study due to its multiple levels of analysis. Gaining insight into and understanding the structure of a complex system and how its interdependent individuals, groups, and institutional components function (or fail to) (Berkwits & Inui, 1998; Hurley, 1999; Yin, 1999; Vaughan, 1992), is vital in order to explore risk management processes within socio-technical systems.

3.3 Research design

Two primary distinctions in designing case studies are 1) between single and multiple case studies, and 2) between holistic or embedded case studies (Yin, 2003; Hartley, 2004). This research design is a multiple embedded case study of two risk regulation regimes in the Norwegian public sector: municipal emergency management and specialized healthcare. A case is defined as the regulator along with the regulated organization in each sector. The embedded case study design means that the single cases entail more than one unit of analysis, as opposed to the holistic case study. Within the single cases, subunits such as regulators, management, and staff are analyzed to arrive at insights into processes across organizational interfaces among system levels in the socio-technical systems of the different regimes.

Figure 3 demonstrates the levels of analysis within the embedded cases and how the phenomenon of risk management is studied in its context. The figure is based on a design-oriented case study perspective and depicts the studies conducted in specialized healthcare and municipal emergency management (Yin, 1999). Moreover, the figure depicts the levels in the respective sectors that have been covered (in grey colour), and the organizational interfaces that are related to the system structure and processes between e.g. regulator and hospital management, between hospital management and division management, and between division management and the staff.

Figure 3. Case study definition, illustrated by the two public risk regulation regimes (inspired by Yin, 1999, pp. 1212).



According to Rasmussen (1997) most previous research and theoretical contributions on risk management processes have been conducted separately within single levels in socio-technical systems. Hence, there is a need for research contributions and designs that examine these processes across system levels. Furthermore, there is a need to map organizational interfaces that are important for risk management (Rasmussen, 1997; Wiig & Aase, 2007; West, 2000), by contributing extensive empirical material collected from the subunits of the system, and analyzed across these units and systems, with the intention of providing a more comprehensive understanding of risk management. Thus the purpose of this multiple embedded case study is to create a comprehensive empirical basis for theory generation and refinement (Vaughan, 1992) of the current model of risk management in socio-technical systems (Rasmussen, 1997; Leveson, 2004).

The study is designed in accordance with principles for theory elaboration (Vaughan, 1992). Theory elaboration is a method for developing general theories of a phenomenon through qualitative case analysis. Theory elaboration begins with a theory or model (e.g. Rasmussen, 1997: p. 185) to guide the research. Cases are chosen because 1) they are potential examples of the research topic; 2) they vary in size and complexity; and 3) they vary in function. The cases are analyzed sequentially and treated independently, so that the idiosyncratic details can maximize the theoretical insight. As the analysis proceeds, the guiding theoretical notions are assessed in light of the results. As an analytic induction the data can contradict or reveal previously undiscovered aspects of the theoretical framework and provide a basis for reassessment or rejection. Moreover, the data can confirm the theory, force the researcher to develop new hypotheses, add details to the theory, models or concepts, and more fully specify it (Vaughan, 1992).

3.4 Case selection

The case selection in this thesis is based on a most dissimilar approach (Andersen, 1997; Stake, 1994; Vaughan, 1992) in order to emphasize the contrasts among the cases. The approach enables a comparison among cases within the state (Hood et al., 1999b) regarding how risks are regulated and managed under highly different public regimes. However, the main reason for selecting most dissimilar cases is not for the purpose of comparison, but to provide empirical material from different areas of the public sector to illuminate the research problem from several angles. The cases are selected because of their variance in the risk profiles involving different regulation regimes. Within specialized healthcare the potential for catastrophe is low, but the there is a high probability of undesired events. Within municipal emergency management some of the hazards present, represent a significant potential of catastrophe; however the probability of undesired events is low (Wiig & Lindøe, 2007b). Moreover, the cases are chosen due to their variance in complexity and size, and in varying organizational form and function. This approach produces not only extensive data, but also different kinds of data, which is beneficial for theory elaboration. First, the multiple units of analysis within the embedded cases produce qualitatively different information, and the case comparison generates contrasts that enable the researcher to discover, reinterpret and improve theoretical constructs. Alternating units of analysis is made possible by the hierarchical nature of organizational forms. Second, when cases vary in their organizational form it permits analysis across varying system levels, this can lead to theory elaboration that more fully merges micro- and macro-level understanding of risk management processes. The approach is also chosen because it is particularly favorable when the research focus on large complex systems which are difficult to study. The shift among

organizational forms can create access to data that had previously been unavailable; and it may enable measurement of aspects that had previously been precluded by the size and the complexity of the research context (Vaughan, 1992).

3.4.1 Municipal emergency management

The structure and complexity of the case study within municipal emergency management is determined by the following hierarchical levels of the Norwegian Governmental system: the governmental level (the Norwegian Parliament, government, and ministries), regulators and associations (national directorates and regulatory authorities), regional regulators (local regulators), municipalities, and public organizations governed by the municipalities, such as public schools and nursing homes. The risk regulation regime in this study covers: 1) the Ministry of Justice and the Police; 2) the Directorate of Civil Protection and Emergency Planning (DCPEP); 3) the County Governor as the governments' chief representative constituting the regional regulatory authority; and 4) the municipal emergency management structure. A case is defined as a regulated municipality along with the regulator (County Governor) responsible for supervising and guiding municipal emergency management. The municipal emergency management regime relies on self-regulation. Self-regulation regimes vary in their structure, enforcement, and rule type (Hutter, 2001b, Rothstein, 2003b). No specific municipal emergency management act exists in the regime. However, according to the Norwegian land use act (Act-1985-06-14-77; DSB, 1997; DSB, 2001) the regulator can object to municipal plans with insufficient risk assessments, or when risks are assessed and accepted by the municipality, but disapproved by the regulator. Internal control was implemented as a vital mean to ensure continuous municipal emergency management processes. The municipal emergency organizations are required to develop risk management systems and procedures to secure and monitor compliance to standards established by the state (Report to the Parliament, 2001-2002:17). The contextual conditions are vital because risks regulated within the regime are rooted within diverse risk sources that vary across municipalities (geographical and natural conditions causing floods, avalanches, and rockslides; infrastructural and industrial conditions causing large traffic accidents, power outages, water supply failures, pollution, and fire). A municipality is supposed to adopt an overview of the local risk sources through risk and vulnerability analyses as well as apply strategies to prevent accidents (Nilsen, 2007). Since the regime involves a variety in risk profiles and characteristics among municipalities, I chose to conduct a multiple case study of six municipalities in two counties. Three case municipalities in each of the counties were selected to provide comprehensive data and enhance the quality of the study by providing elements of contrast

and comparison among municipalities and counties. Furthermore, similar structure of the chosen cases enables the exploration of how contextual aspects, organizational size and regulatory enforcement influenced risk management processes.

In designing the study and selecting the case municipalities, frequent contact with regulators was crucial. I analyzed evaluation reports of all Norwegian county governors when selecting the counties, and then analyzed inspection reports covering most municipalities within the two counties in order to achieve variance in the case municipalities. The selection criteria were population, size, location, risk sources, size of emergency management staff, whether or not a severe accident had occurred within the municipality, and how regulators evaluated plans and exercises pertaining to municipal emergency management. The two counties varied in the number of regulatees and inspectors. Table 1 provides an overview of the six case municipalities.

Contextual aspects	**County 1** (15449 km^2)			**County 2** (7281 km^2)		
Cases	**Case 1**	**Case 2**	**Case 3**	**Case 4**	**Case 5**	**Case 6**
Population	1200	7500	3800	75000	1700	12000
Location	In a fjord surrounded by high mountains	In a fjord surrounded by high mountains	A mix of coastline, fjords, rivers, and high mountains	Costal area, hosting a large town	Inland area	Inland area
Risk sources	Avalanche, rockslide, tunnel risk, fire	Avalanche, rockslide, industrial waste, tunnel risk	Flood, tunnel risk	Infra-structural risk (road traffic, ferry transport), industrial waste	Water reservoir breakage, avalanche, rockslide	Railway accident, industrial waste
Severe accident experience	Yes	Yes	No	No	Yes	No
Plans and exercises	Sufficient	Insufficient	Insufficient	Good	Good	Insufficient

Tabell 1 Contextual description of the six case municipalities

3.4.2 Specialized healthcare

Norwegian public healthcare services consist of primary and specialized services. This study is limited to specialized healthcare. The regime structure is a complex hierarchy governed by the Ministry of Health and Care Services, which runs Norwegian hospitals and the Directorate of Health and Social Services, which performs technical and administrative functions. The Norwegian Board of Health Supervision and the Chief County Medical Officer are the national and local level regulators responsible for supervising health services and healthcare personnel. Norwegian specialized healthcare services are organized in four regions; hospitals are accountable to these regional structures. The hospital organization comprises several levels: top management, division management, department management, and physicians, nurses and other patient treatment providers. Ensuring safe patient care depends on processes across these regime levels. The types of risk covered within specialized healthcare are related to medical errors such as misdiagnosis, malpractice, and medication error. The healthcare system's complexity, sophisticated technology, specialized professions, and tightly coupled interactions between employees and divisions in the hospital hierarchy, causes a complex and interconnected causality of medical errors.

Within the specialized healthcare sector, a case is defined as the hospital organization along with the regulatory authority responsible for supervising healthcare services (Norwegian Board of Health Supervision at the national level and the Chief County Medical Officer at the local level). However, the governmental level is also incorporated in the study via second order data to explore the effects of governmental decisions on framework conditions for the lower system levels. Due to the complexity, interconnectedness, organizational size, and number of sub units involved in the specialized healthcare sector, I chose to conduct one single embedded case study. The objective was to explore all system levels in order to gain in-depth knowledge of the status and influences on risk management processes. The case hospital is a Norwegian regional university hospital with approximately 5000 employees offering specialized healthcare services to a population of 300 000 people. The Norwegian healthcare system consists mainly of state funded hospitals that treat Norwegian citizens at no charge. There is no system of additional private health insurance as there is in many other countries. The specialized healthcare regime is based on self-regulation similar to the municipal emergency management regime. However, a strict legal framework that gives the regulator extensive legislative power to sanction both individuals and organizations characterizes the regime. Hospitals are supposed to establish a risk management system to ensure sound patient treatment and sound error management routines and procedures. The regulator

supervises the risk management systems according to legal demands, and whether individual healthcare employees perform patient treatment according to sound professional standards.

3.5 Data collection

A vital element in conducting and enhancing the quality of case studies is to collect data through a variety of methods (Yin, 1999; 2003, Hartley, 2004, Eisenhardt, 2002). The data collection was therefore conducted using method triangulation (Patton, 1990; 1999; Seale 1999) involving interviews, observation, document analysis, statistical analysis, and application of second-order data. Table 2 summarizes data collection methods and data sources in specialized healthcare and municipal emergency management.

The table illustrates how methods and data have been applied according to the system levels from a socio-technical system perspective. The study triangulated the data sources, to compare and cross check the consistency of information obtained at different times by different means (Patton, 1999; 1990). I compared interview with documentary and observational data; I compared perspectives of different occupational groups at different system levels by triangulating the views of regulatory inspectors, hospital top management, division management, and staff. The triangulation of methods and data sources improves the understanding of discrepancies. Different kinds of data produce different results and capture different parts of the research phenomenon. However, consistency in patterns of data from varying sources, and reasonable explanations of differences among those sources, contribute to the credibility of the results (Patton, 1999; 1990).

Table 2 illustrates that the study of specialized healthcare involves a more comprehensive data material with data collection activities from governmental level to work operation level than the study of municipal emergency management. This is a result of my participation in a research project that yielded extensive data in specialized healthcare.

Public Sector	Specialized healthcare		Municipal emergency management	
System level	**Methods**	**Data sources**	**Methods**	**Data sources**
Government	Document analysis	Krogstad (PhD thesis, 2005), White Paper (NoU, 1997:2), healthcare legislation	Document analysis	Norwegian white papers, legislation, reports to the parliament
Regulator (national/ local) Associations	Document analysis	Labour inspection report, directive 1-54/2000, annual reports, policy documents	Document analysis	Evaluation report (AGENDA, 2002), annual reports, municipal survey (DSB 2002; 2005), Guidelines for regulatory inspection and objection (DSB, 1997; DSB, 1998; DSB, 2001)
	Structured interviews	National level: 4 Local level: 5 Patient representative association: 2	Structured interviews	DCPEP: 2 Inspectors: 8
	Observation	Regulator-hospital meeting	Observation	System audit, and two seminars covering regulatory issues; one arranged by the DCPEP, second by a county governor
Municipality and Hospital	Document analysis	Labour inspection report, annual reports from the Chief County Medical Officer	Document analysis	Inspection reports, municipal plans, emergency plans, crisis information plans, municipal surveys (DSB, 2002; 2005), guidelines for municipal risk and vulnerability analysis, crisis information, internal control.
	Structured interviews	Top management: 6	Structured interviews	None
	Observation	Hospital-regulator meeting	Observation	System audit
Management	Document analysis	Labour inspection report, inspection reports from the Chief County Medical Officer, guidelines for hospital quality committee	Document analysis	None
	Structured interviews	Middle management: 16	Structured interviews	Municipal emergency managers: 10
	Observation	None	Observation	A system audit involving 6 interviews with chairman, chief administrative officer, assistant chief administrative officer, chief fire officer, municipal physician and a rector.
Staff	Document analysis	Regional psychosocial environment survey (Holte et al., 2004).	Document analysis	None
	Structured interviews	Hospital staff: 16	Structured interviews	None
Work operation	Statistical analysis	894 written error reports	Statistical analysis	None

Tabell 2 Data collection methods and data sources summarized for both public sectors

3.5.1 Municipal emergency management

Data collection in municipal emergency management was carried out through qualitative interviews, document analysis, and observations (Patton, 1990; 1999). Prior to the main data collection I interviewed three inspectors from one county governor and two informants from the DCPEP in order to get a sense of the main challenges facing municipal emergency management. I also attended in a seminar on regulatory issues initiated by one county governor, and attended a national seminar covering regulatory issues, organized by the DCPEP. These activities and interviews prior to the main data collection shaped my research problem, helped me choose a theoretical framework, and refined my interview guides. Subsequent to the main data collection I re-interviewed one of the three inspectors in order to test and verify the quality of my findings.

The main data collection was performed over eight months in 2003. The data collection consisted of qualitative tape-recorded interviews with ten municipal emergency managers and four regulatory inspectors. The interviews were followed an interview guide (Appendices I and II) emphasizing the interface between the regulatory authority and the regulated municipalities. The questions pertained to safety learning, risk perception, risk communication, and trust. These issues were included to explore how regulatory inspectors and municipal emergency managers identify and communicate risks (Rothstein, 2003a; Jensen & Kleivan, 1999; Stern & Fineberg, 1996), how municipalities apply risk information for learning purposes (Nilsen, 2007; Reason, 1997), and how the aspect of trust influences risk management activities between the risk regulator and the municipalities (Hawkins & Thomas, 1984). Data collection also involved observation of a planned system audit within one municipality. The system audit included data from interviews with six municipal informants conducted by the regulatory inspectors, in addition to information concerning how the inspectors and emergency managers interact and communicate during the most common inspection activity. The data collection also involved collection of municipal plans, risk and vulnerability analyses, crisis management plans, crisis information plans, annual reports, DCPEP guidelines provided for the municipalities, legislation, policy documents, and inspection reports.

Second-order data were applied to gather information about emergency management processes from Norwegian municipalities and regulatory authorities in general. For this purpose, annual municipal surveys (DSB, 2002; 2005) and an evaluation report (AGENDA, 2002), all conducted on behalf of the DCPEP were integrated in the current study.

3.5.2 Specialized healthcare

Data collection in specialized healthcare covers the system levels of government, regulator, hospital, management, staff, and work operations according to a socio-technical system perspective (Rasmussen, 1997; 2000). A research group consisting of three other researchers and myself carried out the data collection. Extensive material was crucial to exploring the complex structures and processes involved in specialized healthcare. Data were collected through interviews, statistical analysis of reported errors and near misses, observation, and document analysis (Patton, 1990; 1999). The data collection was performed over eighteen months in 2005 and 2006.

Table 2 shows that the application of methods has varied, owing to practicalities, time constraints, and information needs. At the governmental level, document analysis (Healthcare legislation; Krogstad, 2005; Norwegian White paper, NoU 1997:2) was used to describe vital changes the Norwegian healthcare sector has undergone over the past years. At the regulator/association level, we conducted 11 structured interviews (Appendices III and IV) with inspectors at the national and local level and with representatives from the patient representative association. Inspection reports, annual reports and policy documents were analyzed, and I observed a regulator-hospital meeting. Data collection at the healthcare institution level was divided into four subsystem levels: hospital, management, staff, and work operation. At the hospital level, including the top management, we performed six structured interviews (Appendix V) with top managers and division managers, analyzed inspection reports from the Norwegian Labour Inspection Authority and the Chief County Medical Officer, and observed the interaction between the hospital and the regulator in their meeting. At the management level, including hospital middle management, we performed 16 structured interviews (Appendix VI) with head nurses and head physicians at two hospital divisions, and we examined inspection reports and guidelines for the hospital quality committees. At the staff level, we interviewed 16 nurses and physicians within two hospital divisions (Appendix VI). In addition, we studied a regional psychological environment survey (Holte et al., 2004) as second-order data. The work operation level included work operations and processes carried out within the hospital that were at risk for medical errors. To obtain data about such work operations, 894 written error reports from two hospital divisions were registered and analyzed in an Excel spreadsheet.

To summarize, 49 tape-recorded interviews were conducted using the structured interview guides. Seventeen interviews focusing on the relationship between the local health regulator and the regulatee (hospital) with regard to managing errors were performed using an interview guide covering

legislation, error reporting, learning, risk perception, and prevention. Informants included inspectors, the patient representative association, and hospital management. Thirty-two interviews focusing on how two hospital divisions managed errors were performed using an interview guide covering amount and categorization of medical errors, human and organizational factors, learning, power issues, and the regulators' role.

3.6 Data analysis

The way data is analyzed is essential to build theory from case studies (Yin, 2003; Eisenhardt, 2002; Gherardi & Turner, 2002; Miles, & Huberman, 1994a; Vaughan, 1992). However, analysis often turns out to be both complicated and challenging. The current data collection produced an extensive empirical material from multiple researchers, using different methods and data sources within different subunits of the embedded cases. However, data have been systematically displayed and analyzed within cases and across cases (Yin, 2003; Eisenhardt, 2002; Miles and Huberman, 1994a).

3.6.1 Within cases

The cases were analyzed sequentially and independently in order to understand the risk management processes and the characteristics of the two regimes covered in the study (Vaughan, 1992). I started with the municipal emergency management regime and continued with the specialized healthcare regime, before searching for cross patterns between the two.

The analytic processes within the single cases can be described as a ladder of analytical abstraction (Miles & Huberman, 1994b: 92), in which the first rung summarizes and packages the data. I transcribed all tape-recorded interviews, wrote summaries and memos of all relevant quotations from data collection. To analyze risk management processes and activities within each socio-technical system level of the two regimes, data were categorized, structured and analyzed by system level. This step was characterized by interaction between the displayed empirical material and the written analytic text. Patterns and themes that called for new analytic moves entailed new relationships and explanations leading to more differentiated and integrated text (Miles & Huberman, 1994a; 1994b). Furthermore, the analysis involved alternation between units, meaning that data collected within different system levels was analyzed separately before searching for relationships among system levels to identify trends (Wiig & Aase, 2007; Wiig & Lindøe, 2007b).

Data analysis within municipal emergency management was carried out separately within each of the six case municipalities before all of the material was analyzed. The categorization according to themes in the interview guides

provided an oversight that enabled me to assess the findings according to the theoretical framework as the analytic process proceeded (Vaughan, 1992). Moreover, I searched for similarities and differences in population, location, risk profiles, and accident experience among the case-municipalities. This cross-case analysis of the six municipalities constituted the basis for comparison between the two regimes.

Data analysis within specialized healthcare across system levels and organizational interfaces posed a substantial methodological challenge due to the complexity of the data material, covering system levels from government to work operations (Rasmussen, 1997; 2000). To overcome the challenge we applied analyst triangulation, meaning that multiple researchers participated in the analytic process (Patton, 1990; 1999). In the analysis of organizational interfaces, two researchers independently analyzed the material and developed categories according to their general interpretation of the material, not according to specific system levels or interview guide categories (Wiig & Aase, 2007). We then discussed and questioned each other's interpretations, resulting in modified and improved categories (Miles & Huberman, 1994a; Patton, 1999; 1990). Approaching the analytic process of organizational interfaces by a multiple analyst triangulation enriched the quality of the analysis and minimized the potential biases that could come from one person analysing complicated empirical material.

The quantitative data material, covering 894 written error reports collected from two hospital divisions, was analyzed using an Excel spreadsheet. We analyzed the quantitative data by statistical analysis of frequency with regard to error type, error severity, error causality, and personnel categories.

3.6.2 Across cases

The final step in the analytic process consisted of cross-case analysis (Miles & Huberman, 1994a; 1994b; Eisenhardt; 2002; Yin 2003) between municipal emergency management and specialized healthcare. The objective of the cross-case analysis was to create and in-depth understanding of risk management processes across different public sectors by stressing the contrasts between the two cases (Wiig & Lindøe, 2007b).

In the cross-case analysis I searched for patterns across the cases and was forced to move behind the initial impressions of risk management through the application of structured and diverse lenses (Eisenhardt, 2002). Furthermore, the idea of comparing two dissimilar cases is to move towards general theory that spans the levels of analysis by refining theoretical constructs and clarifying their relevance for different organizational forms (Vaughan, 1992).

According to Eisenhardt (2002), the cross-case analysis increases the likelihood of a reliable theory that fits closely with the data.

Different approaches can be employed in cross-case analysis; mine has been to select categories based on an analytic framework developed for comparison among different risk regulation regimes. The Risk Regulation Regime framework (RRR) was used to analyze the cases based on the categories of regime context and regime content. The two dimensions consist of three subcategories; regime context is disaggregated into: 1) type of risk, 2) public preferences and attitudes, and 3) organized interests; regime content is disaggregated into 1) size, 2) structure, and 3) style (Hood et al., 1999a; 2001). The cross-case analysis emphasized similarities and differences among the cases in order to understand how these disaggregated categories shaped understanding of risk among different groups of informants at different system levels.

3.7 Research quality

There exist numerous concepts and definitions of criteria for evaluating the quality of research. These vary according to the scientific traditions and research perspectives supported by different paradigms (Guba & Lincoln, 1994; Miles & Huberman, 1994b). Most of these criteria have emerged out of quantitative research traditions that have traditionally applied the conventional criteria of *internal validity* (the extent to which variations in outcome, dependent variable, can be attributed to controlled variation in an independent variable), *external validity* (the extent to which casual propositions are likely to hold true in different settings, meaning an generalizability of the findings), *reliability* (the extent to which repetition of the application of the same, or the supposedly equivalent, instruments to the same units will result in similar measurement), and *objectivity* (the extent the findings of an inquiry are determined by the subjects and conditions of the inquiry, and not by biases, motivations, interests, or perspectives of the inquirer) (Seale, 1999; Guba & Lincoln, 1994; Miles & Huberman, 1994b). However, these criteria are not necessary applicable for qualitative research traditions. Therefore I apply the criteria suggested by Lincoln and Guba (1985) to establish trustworthiness in the research process as these better reflect the challenges facing the qualitative researcher.

The work of Lincoln and Guba has been particularly influential in developing criteria in qualitative research in order to demonstrate changes that reflect the growth in constructivist and postmodernist influence (Seale, 1999). Lincoln and Guba (1985) argue that establishing the *trustworthiness* of research lies in the heart of issues conventionally discussed as validity and reliability. They

have proposed replacing the conventional formulation with four new terms: *credibility*, in place of internal validity; *transferability* in place of external validity; *dependability* in place of reliability; and *confirmability* in place of objectivity. Lincoln and Guba (1985) also describe ways in which qualitative researchers can operationalize trustworthiness. I have applied these criteria to ensure the quality of my research, and below I will describe how I have addressed them.

Credibility means to perform the research so that the probability for the findings to be found credible is enhanced, and to demonstrate the credibility of the findings by having them approved by the original constructors (Lincoln & Guba, 1985). Possible techniques to enhance credibility are prolonged engagement in the field, persistent observation, triangulation (data, method, investigators), peer debriefing, negative case analysis, referential adequacy, and member checks, showing material such as interviews and research reports to the people to whom research has been conducted so they can approve or disapprove with the way the researcher has represented them. This study therefore applies several of these techniques. Prolonged engagement in the field was ensured by previous research experience within both municipal emergency management (Scharffscher et al., 2001; Nuland et al., 2001) and specialized healthcare (Wiig, 2002) before I started writing the thesis. Persistent observation was ensured by identifying the main characteristics and elements relevant for public risk management and focusing on them to provide in-depth knowledge of the phenomenon. Triangulation was ensured by applying both data and method triangulation in both sectors, and by using analyst triangulation within specialized healthcare. Peer debriefing was ensured by discussing the fieldwork and my empirical findings with colleagues, the patient safety research team, and my supervisors. Referential adequacy (recording or archiving data available for critics) was ensured by tape-recording and transcribing all interviews, storing observational summaries, and all documents. Member checks were ensured by presenting the results in open meetings or by providing the informants with written texts (Seale, 1999; Lincoln & Guba, 1985).

Transferability means that the conclusions of the study can be transferred to other contexts (Miles & Huberman, 1994b). Transferability is not ensured by random sampling but through purposeful sampling, and by providing a detailed and rich description of the setting studied, so that the reader has sufficient information to be able to judge the applicability of the findings and conclusions in other contexts (Seale, 1999; Lincoln & Guba, 1985). In this thesis I have selected the cases using a most dissimilar approach with the purpose of contrasting two cases to improve understanding of risk management processes in different areas of public sector. This provided an

opportunity to consider the transferability of results among different settings of the cases. However, this thesis has illustrated the large diversity within the public sector by studying two different public risk regulation regimes. It is therefore appropriate to reflect on whether or not conclusions are transferable to other contexts, and whether or not it is possible to define the public sector as a single sector. The public sector incorporates completely different areas and regulation regimes with totally different risks. In this thesis, the municipal emergency management and specialized healthcare together provide new knowledge about risk management processes within areas of public sector. Some aspects are similar across public sector regimes while other aspects differ, therefore I have provide a detailed description of context and setting (as far as the article format allows and in thesis Part I), so that the reader can assess the applicability of the conclusions in other settings.

Dependability refers to the consistency of the research process, its stability over time and across researchers and methods (Miles & Huberman, 1994b). Techniques to enhance dependability are overlap in methods (triangulation), stepwise replication, and inquiry audit (Lincoln & Guba, 1985). Within this thesis, data were obtained through triangulation of structured interviews, observation, document analysis, statistical analysis, and second-order data sources. Moreover, stepwise replication was ensured within specialized healthcare by a research team performing separate data analysis prior to joint discussions. Inquiry audit was ensured by enlisting the aid of a supervisor throughout the research process, and by submitting my written analysis for assessment. Within specialized healthcare I was a part of a research team in which the team members and the project manager performed quality control of the research process and product. Furthermore, a reference group at the case hospital ensured the quality of the research process and product by participating in the research design, the selection of hospital divisions, and by giving feedback on results.

Confirmability is related to the freedom of unacknowledged research biases and explicitness about the inevitable biases that exists (Miles & Huberman, 1994b). The major way to establish confirmability is the confirmability audit, similar to the inquiry audit, triangulation, and by keeping a reflexive journal (Lincoln & Guba, 1985). The confirmability audit is sought by giving rich description of methods and procedures, allowing the reader to follow the actual sequence of how data were collected, processed, transformed, and displayed for the specific conclusion. Moreover, all interview data were tape-recorded and stored, with the written documents and observation notes in order to be available for reanalysis. Furthermore, I have kept an audit trail including project proposal, theoretical orientation and reorientation, interview guides, and notes about changes in the research process over the four years of

this study. I have attempted to be explicit and conscious of my personal assumptions, values and biases and how they might have affected the study. This was vital because of my decision to incorporate municipal emergency management and specialized healthcare into the thesis. Because of the two sectors' dissimilarity it was crucial to be continuously aware of this aspect and describe the differences accurately before drawing conclusions.

3.8 Methodological advantages and disadvantages

There is limited research on risk management and regulation processes in the public sector and when I started my research in 2003 I needed to take a broad approach to the field. The flexibility of the case study strategy was crucial in order to adjust the research design as knowledge about the phenomenon improved. My research process began in 2003 with an independent multiple embedded case study in municipal emergency management. However, in late 2004 I was engaged in a patient safety project and realized the potential of incorporating a single embedded case study on risk management processes in specialized healthcare into my thesis, as they were both involved in public risk management and both studies covered similar topics related to my research problem.

The main methodological disadvantage is the inequality between the case studies regarding units of analysis, and the differences in the amount of empirical material between the two cases. In addition, being part of a research team in specialized healthcare, and conducting my research independently in the municipal emergency management, have influenced my research process. These aspects have been subject to considerations about whether or not to incorporate the two independent case studies. I argue for the benefits of the multiple case study to provide new insight into public risk management and regulation in different contextual settings. Different contexts, and the emphasis on exploring two public sectors faced with large diversity with regard to risk sources and risk characteristics is depicted in the thesis' working model (Paragraph 2.6), is one of the study's main methodological advantages. I have explored public risk management in these contexts in order to assess whether or not these findings can be transferred. A multiple case study usually increases the transferability of the findings (Yin, 2003). Furthermore, this study was inspired by Vaughan's (1992) belief that different regulation regimes, organizational forms, and complexity improve the ability to develop better models, concepts and theory. Approaching the field by using contrasting cases has revealed data that would have otherwise remained hidden.

To explore risk management in a socio-technical system perspective constitutes another strength of the study. To study important organizational interfaces in risk management processes it is necessary to explore activities and relations among system levels. This perspective is open to criticism because it is difficult to obtain the high quality information at all units of analysis that enhances the credibility of the findings. To meet this criticism, I have concentrated on the vital issues and processes at the different system levels, described them in detail, in order to establish the clarity of how I have reached my conclusions in this multilevel analysis. I argue that this approach to risk management processes can improve the knowledge of organizational interfaces across system levels, because this is how these processes appear in a dynamic society.

What could have been done differently? The qualitative researcher faces challenges and dilemmas and must assess where to put his or her emphasis and when to finish data collection and analysis. For instance, I could have chosen another research strategy and other data collection methods. Using an ethnographic strategy with a much stronger emphasis on fieldwork could have provided different types of data and knowledge of the risk management processes and decisions. However, due to complexity of the organizations involved, information needs from multiple system levels, time constraints, and my participation in a research project involving predefined constraints regarding research strategy and methods, made an ethnographic approach impractical. The study could also have employed a better method triangulation between quantitative and qualitative methods (Patton, 1999; 1990). My study included triangulation within qualitative methods and a statistical analysis within specialized healthcare. However, I could have applied data material from a survey (Hospital Survey On Patient Safety, developed by Sorra & Nieva, 2004) that we conducted within specialized healthcare (Aase et al., 2007; Olsen, 2007) but data collection was not completed in time for the process of writing articles.

I have tried to conduct my research according to the quality criteria for trustworthiness in qualitative research, as described in Paragraph 3.7. To ensure dependability and confirmability the data collection has taken place over four years. I have used my research team and my supervisors to ensure inquiry audit of my process and my product. However, there may be aspects of change that have been difficult to cover as these sectors changes due to a constant focus on efficiency and production. Nevertheless, recent studies of municipal emergency management (Nilsen, 2007) and specialized healthcare (Olsen, 2007; Høyland & Aase, 2007; Aase et al., 2007) support some of my findings.

4 Results

The overall research problem of the thesis is how organizational interfaces across system levels explain risk management processes in the public sector. This chapter summarizes the research problem in the main findings of the research articles, and the relationship among results documented in the four articles.

4.1 Research articles and research focus

To operationalize the research problem, four research questions are formulated:

1. How can a socio-technical system approach explain important organizational interfaces in public risk management processes?
2. How do different risk regulation regimes shape risk perception among officials and employees within the public sector?
3. How can the interface between risk regulator and regulatee affect risk management processes?
4. How can regulatory enforcement strategies influence information exchange and learning processes within the regulated?

Table 3 provides an overview of the four research articles; their respective foci; the operationalized research question they address; and the specific research question presented in the articles. The overall research problem itself is complex. Therefore the four articles are nested together and are thematically overlapping. Each article is related to one main research question numbered above from 1 – 4 (the bold numbers in column 4), however they help to answer some of the other research questions (illustrated by unbolded letters in column 4).

The four research articles all describe organizational interfaces among system levels in public risk management processes. However, the articles vary in the degree to which they detail the system from the governmental to the street level. Articles I and IV map interfaces in the entire socio-technical system, and Articles II and III emphasize the regulator-regulatee interface.

Articles	Main focus	Sector	Overall research question	Specific research question in articles
I: Fallible humans in infallible systems? Learning from errors in health care	Explores the multilevel system of managing errors in healthcare, and maps organizational interfaces of importance for learning from medical errors.	Specialized healthcare	**1. How can a socio-technical system approach explain important organizational interfaces in public risk management processes?** 3. How can the interface between risk regulator and regulatee affect risk management processes? 4. How can regulatory enforcement strategies influence information exchange and learning processes within the regulated?	The aim of the study is to explore the multilevel system of managing errors in Norwegian Healthcare and to map interfaces of importance for learning from errors.
II: Risk regulation strategies in public emergency management – A learning perspective	Analyzes regulatory enforcements strategies according to their influence on learning within the regulated municipalities.	Municipal emergency management	**4. How can regulatory enforcement strategies influence information exchange and learning processes within the regulated?** 3. How can the interface between risk regulator and regulatee affect risk management processes?	How do regulatory enforcement strategies impact learning processes within the regulated municipalities? What kinds of learning constraints can be identified in the regulator–regulatee interface obstructing learning processes within the regulated municipalities?
III: Patient safety in the interface between hospital and risk regulator	Analyzes how systematic and incidental regulatory activities affect patient safety improvement.	Specialized healthcare	**3. How can the interface between risk regulator and regulatee affect risk management processes?** 4. How can regulatory enforcement strategies influence information exchange and learning processes within the regulated?	How does the interface between hospital and risk regulator affect patient safety? How does systematic or incidental regulatory activities contribute to patient safety? Does an individual or a system focus in the interface have different effects on patient safety?
IV: Risk perception within different risk regulation regimes	Explores how regulatory officials and employees perceive risk within different risk regulation regimes.	Specialized healthcare & Municipal emergency management	**2. How do different risk regulation regimes shape risk perception among officials and employees within the public sector?** 1. How can a socio-technical system approach explain important organizational interfaces in public risk management processes? 3. How can the interface between risk regulator and regulatee affect risk management processes?	How do contextual and content elements of risk regulation regimes shape risk perception among officials and employees within different regimes?

Tabell 3 Article title and main focus, the related overall research question, and the specific research questions presented in the articles

4.2 Results article I

The title of the first article is "Fallible humans in infallible systems? Learning from errors in health care." The article is concerned with Research Questions 1, 3 and 4 (see Table 3). The objective of the article is to explore the multilevel system of managing errors in the Norwegian healthcare and to map interfaces of importance of learning from errors. Despite a substantial literature on patient safety during the last ten years (e.g. Institute of Medicine, 2000; 2001; Rosenthal & Sutcliffe, 2002; Spath, 1999), empirical studies with a multilevel system approach are limited. Such studies are required to improve the understanding of causal chains and spread responsibility throughout all system levels to reduce errors in the sharp end (Ruchlin et al., 2004; Firth-Cozens, 2001; West, 2000). A multilevel case study was therefore conducted using Rasmussen's (1997) socio-technical risk management system as a framework for studying government, regulators and associations, company, management, staff, and work operation.

Results document that different system levels depend on each other in the process of error prevention in Norwegian healthcare. The contextual descriptions of the entire healthcare risk management system revealed that learning from errors is sporadic, individual and occurs separately within the single system levels, with limited information and knowledge exchange among system levels. The healthcare system's ability to prevent and learn from errors was negatively affected by reforms initiated at the governmental level. Structural reforms concerning hospital financing and institutional management altered important framework conditions at all system levels. The reforms resulted in a compound pressure concerning efficiency and safety at hospital, management, staff, and work operation levels. The effects were time pressure, stress, increased workload, and understaffing with a negative impact on the learning conditions within and across system levels. Results also show that the regulator-regulatee interface has limited impact on learning from errors in the healthcare system. Furthermore, the results show that the error reporting system applied in healthcare focuses on statistics and not systematic feedback processes or proactive searches for new risk sources and prevention of errors across system levels.

In sum, the study has shown that the premises on which error prevention in the healthcare system are based, and the processes of importance for error prevention, are all top-down, accumulating expectations and strain towards the lower levels of the system (staff and work operation). As a counteractive measure, the article suggests that bottom-up structures and upward feedback mechanisms should be strengthened. Error preventive needs and constraints should be clarified at the work operation level and communicated to all

upward levels for responses and measures; and safety impact studies should be conducted prior to future healthcare reforms.

4.3 Results article II

The title of the second article is "Risk regulation strategies in public emergency management – A learning perspective." The article answers Research Questions 3 and 4 (see Table 3). Article II examines how government, despite limited legislation, uses enforcement strategies to regulate risks exposed to municipalities. The study explored how risk regulation strategies in the public sector contribute to information exchange and learning on the part of the regulated. The article is based on empirical data from a qualitative multiple case study of six municipalities in two Norwegian counties.

Results were categorized according to two contrasting regulatory enforcement strategies denoted deterrence approaches (representing a formal control style, involving a strict imposition of standards) and compliance approaches (representing an informal style of regulation emphasizing diplomacy, persuasion, and education). The main emphasis in all municipalities was the compliance approaches. The regulators stressed a wide range of activities related to the compliance enforcement strategy, not necessarily with a learning perspective in mind. Nevertheless, by using compliance approaches the regulator provided healthy learning conditions. In organizing the compliance approaches, the regulator emphasized discussion, reflection, and networking in the regulator-regulatee interface. Learning within the compliance approaches fostered a co-operative and open climate, promoted knowledge circulation, and generated knowledge through actions and reflections among individuals, groups and communities of emergency managers and inspectors. The positive influence from compliance approaches on learning depended on the regulatees' priority and willingness to participate in the activities facilitated by the regulator. In contrast, the deterrence approaches implied control activities focusing on compliance. Objections and inspections often caused adjustments, corrections, and attempts to comply, but the activities implied short-term solutions that could not be characterized as learning processes. Aspects of the deterrence approaches could constitute learning constraints in the regulator-regulatee interface. Formal written documents and written information exchange were important aspects, and the inspectors were usually preoccupied with document quality, rather than process quality. Learning constraints were the lack of priority and positions within emergency management in the municipalities. Lack of education and knowledge among municipal employees, and conflicting demands between

emergency management and mandatory work tasks, were also identified as learning constraints within the municipalities.

In sum, the study has shown that different regulatory enforcement strategies have different effects on the regulatee's learning, and that different learning constraints needs to be considered. The article has emphasized the learning processes in the regulated municipalities. Future studies should include how the regulatory authorities and inspectors learn in the regulator-regulatee interface.

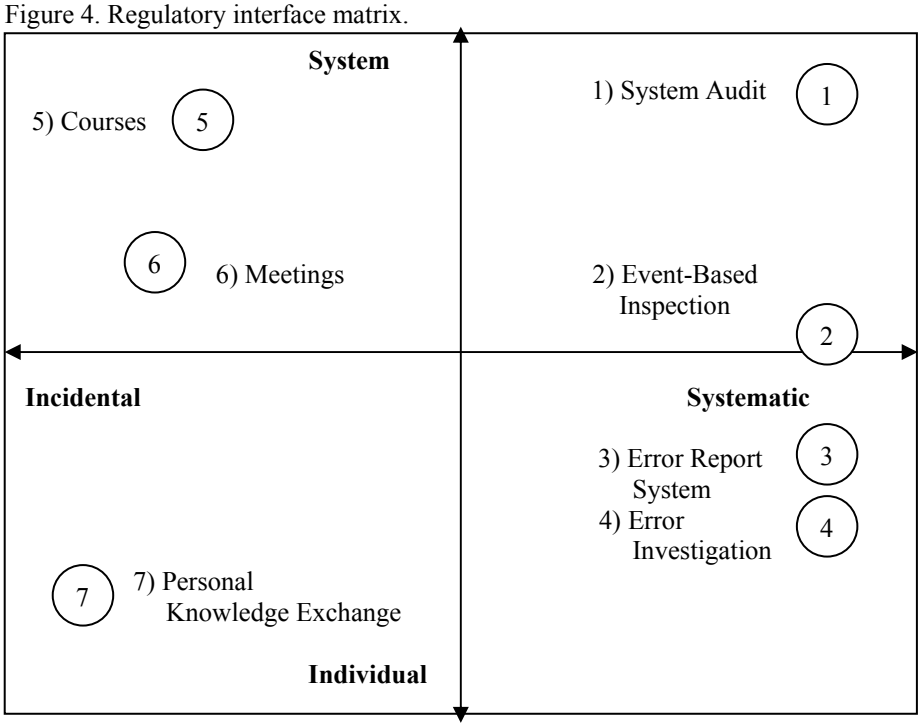
4.4 Results article III

The title of the third article is "Patient safety in the interface between hospital and risk regulator." The article answers Research Questions 3 and 4 (see Table 3). The research design is based on a multilevel case study within the Norwegian healthcare system.

The regulator-regulatee interface is studied using two-dimensions: systematic or incidental regulatory activities (process) and system or individual focus in performing regulatory activities (structure). Four types of systematic activities were covered: 1) system audits, 2) event based inspections, 3) mandatory error reporting system, and 4) error investigations. The systematic activities are performed in multiple ways but are all characterized by formal procedures. In addition, three types of incidental activities were covered: 5) courses, 6) meetings, and 7) exchange of personal knowledge. Figure 4 illustrates how the regulatory activities were categorized according to the process and structure dimensions.

There are two main types of systematic regulatory activities: system audit and event based inspection. The system audit is performed within specific medical domains or organizational levels. The system audit improves patient safety locally, but strives to improve patient safety across intra-organizational borders.

Figure 4. Regulatory interface matrix.



The event-based inspection is reactive and more individually oriented. It is initiated by mandatory error reports (3), patient complaints, or by suspicion of insufficient practice. Based on the severity of the reported errors or complaints, the regulator opens cases (4) against either an individual healthcare worker or the hospital. The incidental regulatory activities (5,6,7) are activities "standing on their own" and are not part of a systematic and consistent "safety-control-system". These incidental activities are characterized by advice rather than control. They improve the knowledge of hospital staff and contribute to positive communication, but they are not predominant activities in the regulator-regulatee interface.

The results demonstrated a paradox in the regulatory legal framework. The law on the one hand focuses on the system responsibility to provide safe health care, but on the other hand provide a more extensive sanctioning repertoire towards individuals than organizations. Inspectors at both national and local levels admit that their ability to sanction individuals is stronger than the system's. However, inspectors argue that individuals are in most cases sanctioned for reasons other than medical error.

In sum, the study shows that the regulatory activities holding a system perspective, such as system audit (1) and courses (5), promote openness and dialogue, and affect patient safety more positively than activities holding an individual perspective. The individual perspective characterizing event-based inspections (2), error reporting (3) and error investigations (4), contributes to underreporting, fear of sanctions, and hampers openness, discussion, and information exchange. From a risk management process perspective, the approaches within the regulator-regulatee interface need improvements to move systematic regulatory activities (event-based inspection, error reporting, error investigation) towards a system perspective, and to emphasize incidental regulatory activities (courses, meetings).

4.5 Results article IV

The title of the fourth article is "Risk perception within different risk regulation regimes." The article answers Research Questions 1,2, and 3 (see Table 3). The article explores how regime contextual aspects (type of risk, public preferences and attitudes, organized interests) and regime content aspects (size, structure, style) shape risk perception among officials and employees within two highly different Norwegian public risk regulation regimes. The article is based on empirical data from a most dissimilar case study approach covering specialized healthcare and municipal emergency management.

Findings in specialized healthcare and municipal emergency management show that risk perception differs among employees and officials within various system levels of the risk regulation regimes. Risks are amplified and attenuated throughout the hierarchical regime structures through risk management processes depending on interaction among humans, organizations, and regulators; external pressure from public and organized interests; technological changes, and financial circumstances causing compound pressure between efficiency and safety. The social amplification and attenuation of risks were more prominent in the specialized healthcare regime.

The study revealed differences in the degree of heterogeneous and homogenous risk perception across regime levels between specialized healthcare and municipal emergency management. We argue that the explanation for this variance lies in the differences between the two regimes. Although both regimes rely on self-regulation, a regime involving complex structures and formal regulatory enforcement of a detailed legislation will involve occupational and hierarchical variations in understanding risk (specialized healthcare). However, a regime with informal regulatory

enforcement styles, limited legislation, and low complexity will imply less variation in risk perception (municipal emergency management). These content-related aspects alone do not shape risk perception; contextual aspects also have to be taken into account. Among contextual elements, type of risks was the most vital factor in shaping risk perception. Within municipal emergency management, risks were usually observable and therefore commonly conceptualized across the regime. Within specialized healthcare, some risks were observable and managed, but several risk types emerged because of the changes and complexity within the regime, and were therefore perceived differently across the regime, if perceived at all.

4.6 Relationship among articles

In sum, the four research articles documented that organizational interfaces across system levels can explain risk management processes in the public sector. Articles I and IV describe organizational interfaces across the entire socio-technical system; how risk amplification and attenuation and learning function in the interfaces; and how regulatory enforcement influences risk management processes in both positive and negative direction. Articles II and III investigated how the organizational interface between regulators and regulatees affects public risk management; how enforcement strategies promote or counteract learning processes; and how a system or individual focus in enforcement activities make different contributions to public risk management processes.

Article I demonstrates how error prevention and safe patient treatment in healthcare depends on processes, decisions, and interdependencies among all system levels. The article also shows how a multilevel socio-technical system perspective applied to risk management processes can be used empirically to map and analyze important activities and barriers among system levels. The analysis reveals difficult framework conditions for safe patient treatment and learning from errors at staff and work operation level. Article IV describes risk management processes across the socio-technical system, using empirical material at all system levels. The article applies the Risk Regulation Regime framework (Hood et al., 1999a; 2001) for comparing risk regulation regimes and analyzes the two public sectors in this thesis. The article explains how the context and content of the two regimes shape how employees and regulatory inspectors perceive and respond to different types of risk. The RRR framework and the socio-technical perspective have several similarities although they appear in different forms. The contextual aspects of the RRR framework: type of risk, public attitudes and preferences, and organized interests correspond to the socio-technical system aspects of hazards at work operation level, environmental stressors in forms of political and public

awareness, and market conditions. Moreover, the content aspects of the RRR framework: size, structure, and style, correspond to the socio-technical system perspective in forms of the regulatory legislation and rule making, the multilevel hierarchical structure, and regulatory enforcement and feedback loops (Rasmussen, 1997; Hood et al., 1999a; 2001). By applying both a socio-technical system perspective and the RRR framework, Articles I and IV contribute to an improved understanding of the relationship between employees and operators in the sharp end, managers and regulatory inspectors in the blunt end, and the organizational systems and contextual settings in which they are all embedded. Both articles show that these organizational interfaces and contexts shape risk perception and the ability to learn from and improve public risk management processes (Wiig & Aase, 2007; Wiig & Lindøe, 2007b).

Articles II and III focus on the regulator - regulatee interface and study how regulatory enforcement through application of different strategies and activities may or may not gain compliance with the law and improve the risk management within the regulated organizations. Individually, these articles approach regulatory enforcement by using different theoretical frameworks to explore and analyze the regulator-regulatee interface. Article II approaches the regulatory enforcement debate by applying a learning perspective to different enforcement strategies (Gherardi & Nicolini, 2000; Hansen et al., 1999; Argyris & Schön, 1996). Article III analyzes the regulatory activities in specialized healthcare according to their systematic or incidental appearance (Kirwan et al., 2002; Hood et al., 1999a; 2001), corresponding to the compliance and deterrence strategies presented in Article II. However, in Article III a second dimension is included in analyzing the regulator-regulatee activities, concerning whether the regulator uses an individual or system focus in the regulatory activities (Reason, 2000, Mulcahy & Rosenthal, 1999; Leape, 1994). Both articles argue that different regulatory enforcement strategies and their related activities may promote or counteract risk management and learning within the regulatee depending on the organizing of the activities; the system or individual focus emphasized by the regulator; and the regulatees' willingness to participate. They also reveal a need to integrate feedback and learning when planning and performing regulatory activities in order to improve public risk management processes.

5 Discussion

The overall research problem of the thesis has been: How can organizational interfaces across system levels explain risk management processes in the public sector? In the following chapter I will discuss the findings, and describe the research contribution made by the thesis.

5.1 Discussion of main findings

The exploration of the two different risk regulation regimes, with contrasting risk profiles (depicted in the thesis working model, Paragraph 2.6), provides a sound basis for exploring risk management processes in the public sector, and explains the importance of organizational interfaces in these processes. The thesis has applied several theoretical contributions to analyze comprehensive empirical data. This makes multiple interpretations of the findings possible, according to several theoretical perspectives. The results could have been interpreted strictly according to a socio-technical system perspective (Rasmussen, 1997; 2000; Rasmussen & Svedung, 2000; Leveson, 2004; Leveson et al., 2005; 2006) emphasizing constraints and adaptations in the organizational interfaces to explain risk management processes in the public sector. Results could have been analyzed according to a learning perspective (Reason, 1997; Gherardi & Nicolini, 2000; Weick et al., 1999), interpreting risk management as a collective learning process in the risk regulation regimes. Otherwise, results could have been analyzed according to risk regulation theory (Hood et al., 1999a; 2001; Baldwin & Cave, 1999; Ayres & Braithwaite, 1992), interpreting the results as a matter of diverse strategies to control risk in different contextual settings.

To structure the discussion, I discuss the findings according to three headlines, drawing on the multiple theoretical contributions applied in the thesis. The first paragraph discusses whether or not the socio-technical system perspective adds to the explanation of risk management processes in the public sector (Research Question 1). The second paragraph discusses whether or not risk perception can be seen as a multilevel process across organizational interfaces in risk regulation regimes (Research Question 2). The third paragraph discusses the importance of the regulator-regulatee interface in risk management processes in the public sector (Research Question 3 and 4).

5.1.1 The explanatory power of the socio-technical system perspective

The application of a socio-technical system approach to real life risk management processes, revealed how work processes at the staff or work

operation level of importance for patient safety or emergency management, depend on framework conditions and decisions established by higher hierarchical levels. The approach enables the study of effects of changes at the governmental level on framework conditions for the lower structural levels exposed to these changes (Wiig & Aase, 2007). These are aspects that are not sufficiently understood in the public sector (e.g. West, 2000). The explanatory power of the socio-technical system perspective is the ability to document the dependability regarding decision-making and information flow at all system levels in a regime. The perspective provides a framework that facilitates a comprehensive understanding of technical, managerial, organizational, and regulatory issues and demonstrates how these factors can be integrated in order to understand and improve risk management processes. Furthermore, the perspective illustrates the responsibility of governments, ministries, regulators, and regulated organizations, and that their decisions and actions cannot be understood separately. They constitute framework condition and constraints that combine to affect the regime's ability to perform safely. Thus, a comprehensive understanding of risk management according to a socio-technical system perspective provides a better understanding of factors that need to be addressed to prevent accidents and improve risk management processes in the public sector (Wiig & Aase, 2007; Wiig; 2007; Wiig & Lindøe, 2007a;b).

In normal work operations the socio-technical system perspective reveals that emergency managers, hospital staff and middle managers on a daily basis had to balance a compound pressure between efficiency and safety. The pressure can be interpreted as a constraint directed downwards from higher levels (Leveson, 2004; Leveson et al., 2005; 2006). More specifically, municipal emergency managers found mandatory work operations more urgent than emergency management tasks that were not established by law (Wiig, 2007). As a consequence, emergency management is vulnerable and is often given less priority than mandatory work operations, due to lack of legislation (Reason, 1997; Rasmussen, 1997). Similarly, specialized healthcare staff must adapt their normal work practice to meet demands to provide safe patient treatment, yet simultaneously treat more patients, faster, and with better quality (Wiig & Aase, 2007; Flin, 2006; Woods 2006). These are conflicting goals, depending on processes across the entire regime, in which a socio-technical system approach documents due to its multilevel perspective, bringing in aspects beyond organizational boundaries. The application of a socio-technical system perspective furthermore enabled the shift of units of analysis, e.g. revealing that the present communication mechanisms across organizational interfaces within the healthcare are insufficient. Due to the focus on different system levels within an organization, the socio-technical system perspective revealed that structural deficiencies and inadequate

managerial decisions within the hospital organization reduced the influence of the mandatory internal risk management system. The system was not able to communicate upwards the constraints and error preventive needs required to invoke necessary changes at the work operation level (Wiig & Aase, 2007).

Exploring risk management processes in a socio-technical system perspective raises a methodological dilemma. Overemphasizing the multilevel perspective may cause a loss of substance knowledge at each system level; overemphasizing the details at each system level may sacrifice oversight. It is difficult to capture processes across the entire healthcare system or the municipal emergency management system. One of the implications is that delimitations are required in order to be specific on the issues to be covered across system levels. Moreover, complex environmental stressors and changes imposed may be difficult to cover at each system level. In the research process this may mean that organizational interfaces, change processes, and environmental stressors must be defined and selected in order to be scrutinized for the sake of a multilevel understanding of their implications. Such prioritization could neglect issues of importance for risk management. Thus it is vital to be transparent in methodological choices and delimitations (Guba & Lincoln, 1994; Miles & Huberman, 1994b).

Both the socio-technical system perspective (Rasmussen, 1997; 2000; Leveson, 2004) and the RRR framework (Hood et al., 1999a; 2001), applied in the thesis, rely on an underlying cybernetic control perspective. One may question whether or not a cybernetic perspective delimits the explanatory power of these models. In the cybernetic perspective it is possible to control risk by feedback processes starting out with defining goals or standards, monitor these, and implement actions to change the behavior of the system. However, in real life risk control processes it may be hard to achieve pre-set standards due to conflicting goals, conflicting viewpoints, and no common agreement among involved stakeholders (Hood, 1996). Le Coze (2007) raises a critique of the application of the socio-technical system perspective, as it is approached by Rasmussen (1997; 2000) and Leveson (2004) classifying these approaches as normative or prescriptive, due to predefinitions in the models and basic components to be filled. He pinpoints that the foundations of these models integrates simplifications for practical purposes, that may put constraints on the data as these should fit the models, rather than the models fitting the data (Le Coze, 2007). However, all models embody simplifications, and the consequence is the need to acknowledge their simplifications, and to assess their advantages and disadvantages, implying that the model is chosen consciously (Hollnagel & Woods, 2006; Le Coze, 2007).

5.1.2 Risk perception as a multilevel process

When exploring risk management processes at different system levels, the empirical results have revealed contrasting views and understandings of risk (Wiig & Lindøe, 2007b), implying a need to interpret how these divergent perspectives emerge, and how social, cultural, and structural factors shape risk perception. By interpreting the results from a risk perception perspective (Pidgeon et al., 2003; Rothstein, 2003a; Kasperson et al., 1988) results demonstrated that risk management processes were affected by amplification and attenuation processes implying that some risks were emphasized while others were de-emphasized in the different regimes.

Results showed that risk perception within the specialized healthcare regime was heterogeneous and varied across regime levels, while risk perception within municipal emergency management turned out to be more homogenous across the regime. The diverse risk profiles between specialized healthcare and municipal emergency management, demonstrated that contextual aspects of the regime in terms of risk types and differences in risk perception invoked consequences for the organizational interfaces across both socio-technical systems. Moreover, the amount of legislation, regime enforcement style, and structural complexity were determinants of the amplification and attenuation processes (Wiig & Lindøe, 2007b).

The specialized healthcare case demonstrated a regime regulating internally imposed risks, in terms of medical errors, often triggered by individual healthcare employees in the sharp end. However, the risk causality was complex because of latent conditions and insufficient processes across organizational interfaces in the entire socio-technical system. Diverse occupational groups across hospital wards and clinics interact in tightly coupled patterns of interaction, often prone to role ambiguity, communication failure, and information loss. The patient treatment moreover depends on complex technology, medication, and more specialized professions. Thus, a common conceptualization of risk is difficult due to the multiple amplification and attenuation stations through which risk is socially processed (Pidgeon et al., 2003; Rothstein, 2003a), such as strong occupational groups and subcultures, powerful regulatory authorities and sanctioning means, media cover, and handover or transitions. These amplification stations cause contradictory risk perceptions among regulators, top managers, middle managers, and occupational groups (Wiig & Lindøe, 2007b; Wiig & Aase, 2007). The heterogeneous risk perception contributes to complicate risk management processes across organizational interfaces. Since there is no common conceptualization of risk, sharing of relevant information is difficult

both vertically and horizontally in the regime, and so is the management of risk (Wiig & Lindøe, 2007b; Wiig & Aase, 2007).

In the municipal emergency management case the usual risk type is observable and externally imposed, but can also be amplified by insufficient local planning, insufficient risk analysis, or understaffing (Wiig, 2007; Wiig & Lindøe, 2007b). For example, during and after risk exposure, amplification processes occur across organizational interfaces through stations such as national and local level regulatory authorities, media, or the public. Consequently, the pressure on the emergency management staff, and street bureaucrat levels will increase. Simultaneously, the pressure upwards the regime increases because the regulator is involved in coordination and managing risk events of a certain extent. Nevertheless, the established regime does not address culpability; and the legislation does not provide the regulator with a legal authority to sanction individuals or the organizations. Instead, the regulator uses the accidents for learning purposes (Wiig, 2007). The regime is prone to risk attenuation due to the legislative framework making the regulator incapable of enforcing authority and sanctions in times of amoral calculators, or when the regulatee, imaged as a political citizen, is not convinced by the regulators' arguments (Kagan & Scholz; 1984; Ayres & Braithwaite, 1992). This legal aspect allows for a regulatee who for multiple reasons disapproves of the performance of municipal emergency management, to do so. This may allow risk conditions to exist within the regulatee. In particular, it makes the regulatee vulnerable when facing unexpected risks dissimilar to the types they have previously experienced. There is a possibility that the regulatee's norms and beliefs with regard to the risk profile (Turner, 2006), will direct attention to and amplify certain types of risk and not others.

5.1.3 The regulator - regulatee interface – does it matter?

Risk regulators are described in the literature as vital institutions in risk regulation regimes (Baldwin & Cave, 1999; Hood et al., 1999a; 2001; Walshe, 2002). The nature of the regulatory institution affects not only the style and strategies employed, but also the success or failure of which regulatory ends are met. This thesis has investigated the organizational interface between the risk regulator and the regulatee by emphasizing systematic and incidental activities performed in the interface; by assessing the regulators' underlying models of understanding errors (Wiig & Lindøe, 2007a); and by exploring different enforcement strategies employed in regulatory practice and their belonging learning effects within the regulatee (Wiig, 2007).

The legal framework regulates responsibilities, systematic processes, and structures for managing risk across organizational interfaces within both studied regimes (Wiig 2007; Wiig & Lindøe, 2007a; b; Wiig & Aase, 2007). The contrasts between the regimes regarding statutory authority and power (Walshe, 2002) implied a substantial diversity in their ability to enforce compliance or deterrence strategies. Neither of the regimes approached regulation strictly according to deterrence or compliance enforcement strategies. Due to absence of an emergency management act, the regulator in municipal emergency management relied on compliance approaches. However, some activities in this interface were characterized as more formal and systematic, implying a stronger control aspect in accordance with deterrence approaches, but not in a strict sense. The success in terms of compliance with regulatory demands and increased level of emergency management performance, depended on the regulatees' willingness to participate in regulatory activities, and the regulators' ability to persuade, educate, and increase commitment within the regulatees (Wiig, 2007). The specialized healthcare regime enforced a strict detailed legislation, enabling the regulator to use deterrence approaches. Still, the regulator preferred compliance approaches in practice (Wiig & Lindøe, 2007a). The healthcare legislation required several systematic activities in the regulator-regulatee interface that usually relied on a distant and formalistic relationship, related to deterrence strategies (Baldwin & Cave, 1999). The performance of the systematic activities was characterized by written information exchange, involving limited face-to-face communication implying proneness to information loss in the interface. The systematic activities increased risk awareness and attention to patient safety issues among the hospital top and middle management. Furthermore, they fostered corrective action to accomplish mandatory work operations in the hospital. The incidental activities in the interface were characterized by openness, dialogue, and

advice. They improved competence among hospital employees and managers. However, the incidental activities were not predominant in the interface, due to fear of conflicting roles among the regulatory inspectors, and changes in the legal framework over the past years. In sum, the regulator-hospital interface did not have substantial influence on patient safety improvement and learning from errors within the hospital (Wiig & Lindøe, 2007a; Wiig & Aase, 2007).

Interpreting risk regulation as a learning process demonstrates the effects of underlying error models (Wiig & Lindøe, 2007a) and the employed regulatory enforcement strategies (Wiig, 2007) within the studied regimes. Regulation then requires vertical information flow across organizational interfaces within the regimes, and requires regulators, organizations, and employees to focus on systems instead of individuals (Allsop & Mulcahy, 1996; Reason, 2000; Berwick, 1989). In addition, learning processes require activities and arenas for reflection and discussion on current practices and improvements (Aase & Nybø, 2004; Gherardi & Nicolini, 2000).

In the specialized healthcare regime, it can be argued that a lack of system perspective, limited provision of advice-related activities and support from the regulator, and limited use of tripartism have obstructed learning processes. It has contributed to fear of blame and defensiveness (Berwick, 1989). Lack of tripartism reduces sources of information and narrows the possibilities of proper oversight (Walshe, 2003). An underlying individually oriented error perspective caused difficulties for the regulator in obtaining vital information due to problems related to managing the dilemma between liability and learning involving mixed roles for the inspectors (Tamuz, 2001; Wilpert, 2006; Reiman & Norros, 2002); it has been documented to cause underreporting and information loss (Wiig & Aase, 2007); and lack of commitment to the formal risk management system within the hospital (Wiig & Lindøe, 2007b). The study revealed a need to integrate a system orientation into regulatory tools and strategies. The regulator should continue the ongoing effort to bridge the gap between an articulated desire for a system perspective and an individually oriented investigative practice (Wiig & Lindøe, 2007a). The specialized healthcare regime holds the legal framework conditions to control risk through responsive regulation (Walshe, 2003; Ayres & Braithwaite, 1992) in terms of sanctioning and enforcement pyramids at an individual and organizational level. However, the regime seems to lack flexibility, and a complete hierarchy of sanctions at the organizational level. This results in an unwillingness to use the strongest sanctioning means against the hospital (Wiig & Lindøe, 2007a), because these consequences are so drastic that it is hardly ever appropriate to use them (e.g. closing a hospital ward or a hospital).

Within municipal emergency management the regime directed responsibility towards the system, preparing the municipal organization to manage risk. This regime to a certain degree involves tripartism in the form of for example efforts from volunteer organizations during emergencies. The regulator applies a mix of regulatory activities in the interface and promotes persuasion, education, and facilitates several learning arenas for information flow across the regulator-regulatee interface. These activities were described and evaluated as positive, promoting discussion, reflection, increased competence, and experience transfer in the regulator-regulatee interface. The compliance approaches thus contributed to defining regulation as a learning process (Gherardi & Nicolini, 2000; Reason, 1997). The activities categorized according to the deterrence approaches implied short-term adjustments and were not defined as a learning process. Learning barriers such as time pressure, competing demands, and financial circumstances were identified in the regulator-regulatee interface, complicating the improvement of risk management processes (Wiig, 2007).

The most prominent aspect of the regulator-regulatee interface concerns the different learning impacts of practicing different regulatory enforcement strategies. In both regimes, the compliance approach activities had a stronger tendency to invoke second-order learning processes in the regulatees, involving new ways of solving problems, compared to deterrence activities. The deterrence activities contributed to first-order learning processes, characterized by local adjustments and adaptations to regulatory demands rather than engaging the regulatees in second-order learning processes involving a long-term improvement perspective. The discrepancy between the regimes was illuminated by the diversity in regulatory practice. More specifically, regulatory practice in specialized healthcare was characterized by signs of deterrence, compared to the municipal emergency management, and learning processes were sporadic, individual, and occurred separately within the system levels (Wiig & Aase, 2007). Several factors beyond regulatory enforcement strategies, contribute to determine the success or failure of learning processes. However, this thesis found that the regulators' choice and practice of regulatory enforcement strategies, influence the quality of regulatees' learning processes (Wiig & Aase, 2007; Wiig, 2007; Wiig & Lindøe, 2007a;b).

Thus, keeping the learning aspect in mind and interpreting it according to the RRR framework (Hood et al., 1999a; 2001), one question is the degree to which the framework incorporates a learning perspective. This thesis documented that the size element, involving diverse legal framework; systematic/incidental activities; and sanctioning power (Wiig & Lindøe, 2007a; Wiig, 2007); the style element and the use of deterrence or compliance

enforcement strategies (Wiig, 2007; Wiig & Lindøe, 2007b); and the structure element and the degree of structure complexity, communication mechanisms, and information flow altogether were regime content elements affecting the regulatee's learning processes and barriers (Wiig & Aase, 2007; Wiig & Lindøe, 2007b). The thesis also showed that the regime context in forms of the type of risk and media cover, were related to learning implications. Learning processes depended on the sharp end – blunt end dimension and whether or not people are exposed to risk (Wiig & Lindøe, 2007b; Slovic, 2000), and need strategies to cope with risk in their work. Simultaneously, the fear of media cover implied negative learning implications due to collegial cover-ups and limited discussion of errors (Wiig & Aase, 2007). These learning aspects of regime content and context are relevant when performing the control components (standard setting, information collection, and behaviour modification) in regulatory practice. According to the thesis results, an explicit discussion regarding the extent to which the control components should emphasize the learning aspect would strengthen the RRR framework (Hood et al., 1999a; 2001).

5.2 Research contribution

In sum, the thesis contributes to the study of risk governance (Renn, 2005; 2007), by providing new knowledge on risk processes in vertical governance structures in two risk regulation regimes. The thesis has contributed with an empirical exploration of organizational interfaces from a socio-technical system perspective (Rasmussen, 1997; 2000, Leveson, 2004). There is a lack of multilevel empirical studies of risk management in the public sector, and this thesis studies practical risk management processes across system levels. The emphasis on organizational interfaces has refined the socio-technical system perspective by providing new knowledge about implications of structures (e.g. legal framework, institutional design, framework conditions, defined roles, and responsibilities) and processes (e.g. interaction among subsystems, regulatory practice, information flow, role conflicts), defining the organizational interfaces as key transitions points among the different organizational subsystems and their members, involved in risk management processes. Thus, the thesis has improved our theoretical and empirical conceptualization of the organizational interface concept.

The research contribution refines risk regulation theory by incorporating the learning perspective. The thesis explores risk regulation as a learning process by studying learning effects from different regulatory enforcement strategies and activities in the regulator-regulatee interface. Moreover, it has called for an explicit development of the RRR framework (Hood et al., 1999a; 2001) to

integrate learning implications from content and context aspects on the control components in performing regulatory practice.

By approaching risk perception from a broad perspective, the thesis adds to the risk perception research (Kasperson et al., 1988; Pidgeon et al., 2003), viewing it as a multilevel process depending on structural, cultural, and process elements across organizational interfaces. The thesis has explored risk perception across regime levels and pinpointed how the contextual and content aspects (Hood et al., 1999a; 2001) of the regimes themselves shape risk perception of inspectors and employees. Only a few studies (Rothstein, 2003a; Hutter & Lloyd-Bostock, 1992) have addressed risk perception in a similar manner. Thus, the thesis provides a foundation for further theoretical and empirical development of a multilevel understanding of risk perception among diverse occupational groups across levels of risk regulation regimes.

6 Conclusion

In this chapter I answer the overall research problem: how can organizational interfaces across system levels explain risk management processes in the public sector? Moreover, I recommend relevant implications for risk management processes in the public sector, and suggest focal areas for further research.

6.1 Answering the research problem

This thesis has demonstrated that risk regulation regimes will be exposed to pressures from internal mechanisms (e.g. occupational subcultures, regulatory styles, underreporting) and external mechanisms (e.g. public attitudes, governmental reforms, media cover), with consequences that have to be managed across organizational interfaces. Thus, the understanding of vertical risk governance processes and organizational interfaces is vital, and particularly important in relation to restructuring processes in the public sector (e.g. New Public Management reforms).

The socio-technical system perspective is appropriate to structure and understand risk management processes across multiple organizational interfaces. It structures both theoretical and methodological choices in research on vertical risk governance processes. These processes across organizational interfaces moreover shape risk perception among officials and employees in different risk regulation regimes. By improving knowledge on social, cultural, structural, and contextual determinants of risk perception one may understand why certain types of risks are emphasized and managed, while others are neglected in socio-technical risk management processes.

The regulator-regulatee interface can both facilitate and obstruct risk management processes. The study of activities in the interface between regulators and regulates documented that learning and improvement within the regulatees depended on compliance enforcement strategies; system oriented error models; and frequent activities both systematic and incidental in the interface. Deterrence enforcement strategies along with individual error models and sporadic regulatory activities counteracted the influence from the regulator-regulatee interface on long-term improvement and learning in the risk management processes.

To conclude, the study of two most dissimilar cases has demonstrated that contrasts between structures (e.g. legal framework, institutional design, framework conditions, roles, and responsibilities) and processes (e.g. interaction among subsystems, regulatory practice, information flow,

conflicting objectives) provided new insight into how organizational interfaces add explanatory power to the success or failure of risk management processes, with potential relevance beyond municipal emergency management and specialized healthcare. Socio-technical systems involving a comprehensive legal framework, defined roles and responsibilities; complex institutional design; and tightly coupled interaction processes among diverse occupational groups create multiple subsystems and organizational interfaces in which risk management processes are highly dependent on common conceptualization of risk, sufficient communication mechanisms, and continuous information flow across the organizational interfaces to succeed. Socio-technical systems involving less structural complexity; fewer legally predefined roles and responsibilities; and more loosely coupled interaction processes create fewer interfaces among subsystems and their members, implying better conditions for communication processes, information flow, and oversight. This leaves the organizational interfaces less prone to contribute to complicate the risk management processes. According to the thesis findings, a multilevel understanding of organizational interfaces requires a broad theoretical perspective in order to interpret their implications from the governmental level in the blunt end to street level bureaucrats in the sharp end. Thus, the research results create foundation for further theoretical and empirical development, and suggest focal areas in order to develop an understanding of public risk management as a multilevel process.

6.2 Implications for risk management in the public sector

The implications are discussed according to the system levels in the thesis working model (Paragraph 2.6).

Governmental level:

- Public sector should improve the management of future change processes by incorporating risk management impact studies prior to implementing changes and reforms.
- The governmental level should adopt a multilevel risk management perspective. Changes and reforms imply new administrative structures, responsibilities, and duties within different regime levels that may represent alterations of organizational interfaces with possible consequences for the ability of regulators, managers, and employees to relate their risk management work to other system levels.
- The government should focus on the role of slack (time, personnel, resources), the importance of competence, and sound communication channels as success factors in order to maintain framework conditions

for improved risk management processes in complex socio-technical systems.

Regulatory level:

- The specialized healthcare regulator should make stronger use of tripartism and empowerment towards the regulated organizations. Tripartism would favour stronger involvement of e.g. patients and patient representative associations, and regulators responsible for occupational health and safety regulation that could extend the regulator's sources of information and improve their oversight. Empowerment could imply an increased focus on long-term improvements within the regulatees, beyond short-term adjustments demonstrated in present practice.
- A promotion of empowerment along with system-oriented models of medical errors within specialized healthcare would be in accordance with the idea of regulation as a continuous learning process. By emphasizing learning aspects, the thesis has showed that regulators should adopt these in order to improve regulatory practice.
- Due to the absence of legislation, the aspect of voluntariness was predominant in the regulator-regulatee interface within the municipal emergency management. An implementation of an emergency management act is recommendable. It would be beneficial and provide improved framework conditions for regulatory compliance for both regulators and regulatees. To provide a hierarchy of sanctions for the regulator would strengthen the regulator's position in enforcing regulations. Simultaneously, the regulator should continue to facilitate learning arenas and activities that are vital for information flow, second order learning processes, and homogenous risk perception across the regulator-regulatee interface.

Organizational level:

- The internal risk management system in the hospital should increase its commitment to managing medical errors. It should analyze repetitive errors; search for trends and emerging risk sources; and it should emphasize experience transfer across organizational interfaces more strongly.
- Hospital top management should continue to emphasize patient safety as a competitive advantage. However, specific strategies, goals, and resources visible at lower organizational levels (managerial, staff, and work operation) should be developed in order to counteract the conflicting goals of patient safety and efficiency in the sharp end.

- Within municipal emergency management, financial resources should accompany an implementation of the recommended emergency management act. Such a legal act along with financial resources would give emergency management processes equal status with other mandatory work processes.

Managerial level:

- Inspection reports, distributed by the regulator, should be applied more systematically at the managerial level to increase knowledge of common errors across hospital divisions and wards. Similarly inspection reports from divisions across Norwegian hospitals are published and available at the website of the Norwegian Board of Health Supervision.
- Patient safety issues should be included and discussed regularly in shift handovers, managerial meetings, involving feedback from error reports followed by discussions of possible preventive measures.
- Municipalities should establish learning arenas to bring together representatives from different sub-sectors. Learning arenas will increase the competency within emergency management, bring in multiple perspectives, and reduce the reliance of emergency management on certain individuals.

Staff level:

- There is a need to develop learning arenas at the staff level within specialized healthcare. These learning arenas should be based on multidisciplinary teams, gathering members from several professional groups. Presently, learning processes suffer from cultural diversity between professional groups, cover-ups, different risk perception, and different thresholds to report errors. Multidisciplinary teams will improve common understanding of medical errors, and learning arenas such as plenary sessions, minor group meetings within or across wards should be established. Learning arenas could furthermore counteract the characteristics a blame culture by addressing medical errors from a system perspective, sharing experiences, and improving current practice in a healthy learning environment.
- A stronger collaboration among emergency managers across neighbouring municipalities should be promoted because of limited number of emergency management positions in each municipality.

Work operation level:

- There is a need to strengthen bottom-up structures and communication mechanisms across organizational interfaces in the specialized healthcare regime. Measures are needed to ensure sufficient functioning of communication structures and mechanisms. The mandatory error reporting system and the hospital's internal risk management system, should be more involved in upward information flow to decision-making levels in the socio-technical system. Decision-making levels need to act on information about error preventing needs and constraints and initiate appropriate responses to improve risk management at the work operation level.
- In practice, the staff and work operation level need greater reserve capacity to enable work operations beyond the short-term production objective. More specifically, this means providing sufficient time to write error reports and provide feedback to build a stronger reporting culture; to reduce understaffing on wards with constant patient overload; and to train and educate employees to manage sophisticated technology, new procedures and routines, new medications, and to improve teamwork skills.

6.3 Further research

Further studies are recommended to increase the knowledge of organizational interfaces in socio-technical systems involved in risk regulation regimes. I suggest the following areas for future research:

- Current research results should relate the empirical material to survey results obtained by a Hospital Survey On Patient Safety conducted in 2006 (Olsen, 2007; Aase et al., 2007). Moreover, it would be beneficial to perform a similar risk management survey within municipal emergency management to include street level bureaucrats and end users.
- To explore the long-term implications of New Public Management reforms on organizational interfaces involved in risk management processes in different public sectors (Ferlie, 2007; Hale, 2006).
- To improve the knowledge of the relationship between regime content and context (Hood et al., 1999a; 2001), and learning processes (Gherardi & Nicolini, 2000; Aase & Nybø, 2004) within different risk regulation regimes.
- To study the role of knowledge brokers (Wenger, 1998) in organizational interfaces within complex socio-technical systems (Wiig & Aase, 2007).

- To conduct studies on how regulators learn and improve their regulatory practice in the regulator-regulatee interface (Reason, 1997; Wiig, 2007).
- To develop tools to visualize risk amplification and attenuation processes (Rothstein, 2003a; Kasperson et al., 1988; Pidgeon et al., 2003) through action research involving different regime levels in order to promote common conceptualization of risk.
- To perform comparative studies of contrasting risk regulation regimes (Rothstein et al., 2006) to reveal strengths and weaknesses of self-regulation (Hutter, 2001b; Rothstein, 2003b) in the public sector.
- To include stakeholders beyond the regulator and the regulated (Drennan & McConnell, 2007) to explore the role of tripartism in public sector risk management processes (Walshe, 2003; Ayres & Braithwaite, 1992); and perform specific studies on current practice of tripartism within specialized healthcare and municipal emergency management, including stakeholders such as hospital patients and municipal citizens in the studies.

7 References

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Part II

List of articles

Article I
Wiig S. & Aase, K. (2007). Fallible humans in infallible systems? Learning from errors in health care. *Safety Science Monitor,* (Fall 2007, Forthcoming).

Article II
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Article IV
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Article I

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Fallible humans in infallible systems? Learning from errors in health care

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Abstract

This study both explores the multi-level system of managing errors in Norwegian health care and maps interfaces of importance for learning from errors. A multi-level case study has been conducted using Rasmussen's (1997) socio-technical risk management system as a framework for studying the following levels: Government, regulators and associations, company, management, staff, and work operations. The results document that different system levels are dependent on each other in the process of error prevention in Norwegian health care. Healthcare reforms constitute framework conditions that complicate error management, and the blame culture characterising the healthcare system counteracts learning from errors. The systems for error prevention and learning from errors are fallible due to imperfections at all levels. Fallible humans are prone to cultural aspects such as underreporting and occupational differences, organisational aspects such as workload and error reporting demands, and societal aspects such as healthcare reforms' demand for higher production and an individualistic control system.

1. Introduction

Treating patients is a complex process involving sophisticated technology, dangerous medicines, diverse patients, multiple work processes, and various professional disciplines experiencing an increasing level of specialization (Spath, 1999; West, 2000). Delivering health care in a wider context is even more complicated, involving governmental healthcare legislation and budgets, regulatory authorities' control activities, and a loosely coupled system of numerous organisations. This paper studies the management of errors in this setting. By errors we mean misdiagnosis, medication errors, or erroneous processes of medical treatment in general. The aim of the study is to explore the multi-level system of managing errors in Norwegian health care and to map interfaces of importance for learning from errors.

Norwegian health care is currently subject to structural changes involving reorganizing and cost effectiveness so that more patients can be treated with better quality and the same number of employees. Presently, not only do inspections from the regulatory authorities indicate errors and deficiencies in health care, but there is also a growing media focus on patient safety. Given these framework conditions, the system of managing errors in the healthcare sector involves several challenges. Despite an increasing workload, employees in healthcare institutions are supposed to report, correct, and learn from errors. Healthcare institutions are expected to build routines and systems to report, analyse, and learn from errors, despite reduced

budgets. Regulatory authorities must maintain their systems for reporting of serious errors and their ability to sanction employees and institutions, despite an increase in cases.

Viewing error prevention as a continuous process, rather than a product of certain activities or behaviours (e.g., Gherardi & Nicolini, 2000), involves the exploration of the entire healthcare system to map dependencies and interfaces that influence the error prevention process. Furthermore, a process view implies that learning from errors is a collective capacity that produces organisational and inter-organisational error prevention practices. Given the complexity of the healthcare system, producing such a collective capacity involves learning processes across different levels and occupational groups.

2. Previous research

2.1 Error prevention as a multi-level process

Different levels of healthcare processes and framework conditions constitute what Rasmussen (1997) has named a socio-technical risk management system, involving the following levels: Government, regulators and associations, company, management, staff, and work operation. All levels are interconnected, and, in different ways, will influence the bottom-level work operations. At each level, changes or environmental stressors may be introduced, including new legislation, a changing political climate, changing market conditions, changes in company competency levels, and technological changes. Given the interconnectedness between levels, such changes will affect the entire system. A few studies within other industries have been conducted using this relational approach to safety (van der Geest et al., 2003; Leveson, 2004; Snook, 2000).

Despite a substantial literature on patient safety during the last ten years (e.g., Kohn et al., 2000; Rosenthal & Sutcliffe, 2002; Spath, 1999), empirical studies with a multi-level system approach are limited. Most likely due to the complexity of the healthcare system, studies are conducted within one level of the system, often with an organisational, group or individual focus (Ruchlin et al., 2004). Research has often failed to follow the causal chains back to the managers, civil servants, or politicians who may have failed in their decisions to provide an environment conducive to patient safety (West, 2000). Firth-Cozens (2001) argues that using the systems approach is important for spreading responsibility throughout all levels and thereby reducing the focus on errors in the sharp end.

2.2 Error prevention as a learning process

The ideal error prevention approach is to view errors as symptoms of underlying problems so they become sources of information to understand how systems work. Accidents and near misses should be seen as useful tools that contribute to defining margins of risk and safety and to learning how to prevent harm (Edmondson, 2004; Johnstone & Kanitsaki, 2005; Morath & Turnbull, 2005). This approach is based on the premise that humans are fallible, errors must be expected, and individuals' poor performance is a non-issue; instead, the focus is on the failure in the group, team, organisation or procedure. Emphasis is on feedback from work processes, accurate

information, rules of inference, reflection and discussion between colleagues, and possibly dialogue with users (Allsop & Mulcahy, 1996).

Research on patient safety has applied the concept of the clinical microsystem (Mohr et al., 2004) as a framework for approaching learning from errors. Healthcare organisations comprise smaller interconnected microsystems; some argue that opportunities for cross-microsystem learning are essential for learning about the systemic errors within institutions. Fostering collaborative relations among microsystems should be an important goal for healthcare organisations (Mohr et al., 2004). The microsystem approach has much in common with theories of communities of practice (e.g. Brown & Duguid, 1991; Gherardi, 2000; Wenger, 1998; Wenger & Snyder, 2000). Communities of practice are informal groups of people that evolve over time on the basis of shared expertise and joint activities and where dialogue, analysis, reflection and socialization are important learning conditions (Aase & Nybø, 2004; Aase & Tjensvoll, 2003). Other studies have highlighted the role of teamwork to improve learning and error prevention (Adorian et al., 1990; Firth-Cozens, 1998; 2001; Reith, 1998). Due to the size and complexity of the healthcare system, Firth-Cozens (2001) argues that, unless an appropriate culture and structures are created to enable smaller groups and teams to create safe work practices, error prevention can only be achieved to a limited extent by interventions at an organisational level.

2.3 Barriers to error prevention

According to Leape (1994; 1999), there are several reasons for the substantial error rate within medical practice. One reason is a lack of awareness regarding error-related patient injuries within medical practice. Another reason is that most errors do no harm. But the main reason is found in the culture of medical practice. Medical personnel are socialized to strive for error-free practice during education; role models in medical education reinforce the concept of infallibility; and in the hospital practice, the sense of duty to perform faultlessly is strongly internalized. This need to be infallible generates a pressure that encourages intellectual dishonesty; that is, to cover up rather than admit mistakes. Almost every medical employee experiences mistakes that harm patients in their career, but the fallible physician rarely admits or discusses errors (Leape, 1994; 1999). Physicians also find it difficult to criticize a colleague's unprofessional or unethical conduct (Aasland & Førde, 2005) due to a widespread tradition in health care of naming, shaming and blaming individuals involved in unsafe acts (Reason, 2000). The blame culture (Morath & Turnbull, 2005; Vuuren, 1999) has counteracted the exploration of weaknesses in work processes at different levels, causing a loss of rich information about how individuals, medical work, and organisational processes interact. The implication for learning from errors is that individuals may learn from errors and change their practice, but the adjustments often take place in a vacuum. Lessons learned are shared privately (if at all), and external evaluations of what went wrong seldom occur (Førde, 2000; Leape, 1994; 1999; Vuuren, 2000).

Errors also tend to be underreported (Kohn et al., 2000). In Norway, research indicates that more than half of the mandatory reportable errors are not reported (Aasland & Førde, 2005). Despite a substantial change in thinking in recent years with regard to practicing error management in health care, the fear of negative

reactions, media publicity and being criminalized still leads to underreporting (Firth-Cozens, 2001; Johnstone & Kanitsaki, 2005; Mulcahy & Rosenthal, 1999). Studies on cultural barriers to error reporting (Waring, 2005) revealed that physicians viewed errors as an 'inevitable' and unmanageable feature of medical work; reporting was thus regarded as pointless. Reporting was also discouraged by an anti-bureaucratic attitude and by rejection of excessive administrative duties.

3. Methodology

A study of the multi-level system of managing and learning from errors in health care requires multiple methods and multiple data sources. A qualitative research perspective and methods were chosen to explore and map the dynamics of organisational change and learning in health care to provide insight into organisational matters, error management processes, and discourses (Benson-Rea & Myers, 2006). More specifically, our main research design is a case study approach (Ragin & Becker, 1992; Yin, 1994; 1999; 2004) within a regional Norwegian hospital whose regulatory authorities belong to both local and national levels. We apply the case study approach due to the characteristics and conditions of the healthcare system, which comprises multiple components, complex processes, and rapid changes. The case study approach is particularly applicable for gaining insight into, and understanding the structure of, a complex system and how its interdependent individuals, groups, and institutional components function (or fail to function) together (Berkwits & Inui, 1998; Hurley, 1999; Yin, 1999). The study covers the levels of government, regulator, company, management, staff, and work operations according to a socio-technical system perspective (Rasmussen, 1997). Table 1 shows the different system levels with the accompanying data collection methods, data sources, and informants included in the case study.

System levels	Methods	Data sources and informants
Government	Document analysis	Krogstad (PhD thesis, 2005), White Paper (NoU, 1997:2), healthcare legislation
Regulator (national/local) Associations	11 structured interviews (A)	National level: 4 Local level: 5 Patient representative association: 2
	Document analysis	Labour inspection report, directive 1-54/2000, annual reports, policy documents
	Observation	Regulator-Hospital meeting
Hospital	6 structured interviews (A)	Top management: 6
	Document analysis	Labour inspection report, annual report from the Chief County Medical Officer
	Observation	Regulator-Hospital meeting
Management	16 structured interviews (B)	Middle management: 16
	Document analysis	Labour inspection report, inspection reports from the Chief County Medical Officer, guidelines for hospital quality committee
Staff	16 structured interviews (B)	Hospital staff: 16
	Document analysis	Regional psychosocial environment survey (Holte et al., 2004).
Work operations	Statistical analysis of error reports	894 written error reports

Table 1. Data collection methods within a multi-level system approach.

Data were collected using method triangulation of qualitative and quantitative methods, such as interviews, statistical analysis of reported errors and near misses, observation, and document analysis (Patton, 1990; 1999). Within the different system levels, the application of methods has varied (as illustrated in Table 1) due to practicalities, time constraints, and information needs. At the governmental level, document analysis (Health care legislation; Krogstad, 2005; Norwegian White paper, NoU 1997:2) was used to describe the vital changes the Norwegian healthcare sector has undergone in past years. At the regulator/association level, we performed 11 structured interviews (interview guide A) with inspectors at the national and local level regulator and with representatives from the patient representative association. Furthermore, documents such as inspection reports, annual reports and policy documents were analysed, and the first author observed a regulator-hospital meeting.

Data collection at the health care institution level was divided in four sub-system levels: hospital, management, staff, and work operation. At the hospital level, which included the top management, we performed six structured interviews (interview guide A) with top managers and division managers, analysed inspection reports from the Norwegian Labour Inspection Authority and the Chief County Medical Officer, and observed the interaction between the hospital and the regulator in a hospital-regulator meeting. The management level included hospital middle management, in which we performed 16 structured interviews (interview guide B) with head nurses and head physicians at two hospital divisions, and we conducted document analysis of inspection reports and guidelines for the hospital quality committees. At the staff level, we interviewed 16 nurses and physicians within two hospital divisions (interview guide B). In addition, we analysed a regional psychological environment survey (Holte et al., 2004) as second order data. The work operation level included work operations and processes carried out within the hospital that were at risk for medical errors. To get data about such work operations at the case hospital, a total of 894 written error reports from two hospital divisions were registered and analysed in an Excel–database.

A total of forty-nine tape-recorded interviews were performed using two structured interview guides. Seventeen interviews focusing on the relationship between the local health regulator and the regulatee (hospital) with regard to managing errors were performed using interview guide A (legislation, error reporting, learning, risk perception, and prevention). Informants included inspectors, the patient representative association, and hospital management. Thirty-two interviews focusing on how two hospital divisions managed errors were performed using interview guide B (amount and categorization, human and organisational factors, learning, power issues, and regulators role).

Qualitative data were analysed by transcribing summaries and memos with relevant quotations from all data collection activities. To enhance the credibility of the qualitative analysis, the two authors used a multiple analyst approach to review the findings. This technique is termed analyst triangulation (Patton, 1990; 1999), and both authors independently examined the total amount of data material. To analyze processes and activities important for error management within each system level, data were categorized, structured and analysed according to system levels and themes within the structured interview guides. To analyse the data material across system levels and map vital system interfaces of importance for error management involved a substantial methodological challenge due to the complexity of the data material. In the first stage of system interface analysis, both researchers independently analysed the material and developed categories according to their interpretation of the material as a whole, not according to specific system levels. In the second stage, the researchers discussed and challenged each other's interpretation of the material, resulting in modified and improved categories (Miles & Huberman, 1994). Quantitative data were analysed by statistical analysis of frequency with regard to error type, error severity, error causality, and personnel categories. Within analytic triangulation, it is common to have those who were studied review the findings. In this study, results were presented at the hospital in several announced open meetings, and informants were

given the opportunity to react to the findings and the researchers' descriptions (Patton, 1990; 1999).

4. The health care risk management system

The Norwegian health care risk management system is presented by giving contextual descriptions of the different system levels with regard to framework conditions and learning from errors.

4.1 Governmental level

The governmental level involves legislation and governmental funding within five health regions, where hospitals are organised separately from primary care. The Norwegian healthcare sector has undergone several changes in the last ten years. New public management and its characteristics of cost control and effectiveness form the backdrop of the major changes at the governmental level (Krogstad, 2005). Three structural reforms are essential: 1) A change in hospital financing, which had a central purpose to reduce patient waiting lists, was implemented in 1997. This reform was intended to pay the hospitals based on the number of patients treated, thereby reducing the previous over-all payment to the hospitals. 2) A change in institutional management, first suggested in 1997 (NOU 1997:2) and followed up by a new law (Specialized Health Service Act, 1999); its rationale was to strengthen the leadership and management as a response to the growing complexity in the hospital organisations. This reform represented an explicit desire for increased efficiency and an inexplicit shift from clinical to managerial rationality. 3) A change in hospital ownership and central management, implemented in 2002, which involved a transfer of hospital ownership from the counties to the central government. This reform placed the responsibility with one owner. Furthermore, the hospitals were organised as enterprises that were legal subjects and no longer subjects to local political interference or influence (Krogstad, 2005).

4.2 Regulatory level

The Norwegian Board of Health is responsible for general supervision of health and social services at a national level. At a local level (county), this responsibility is delegated to the Chief County Medical Officer. Normally, it is the local-level regulator[1] who interacts with the hospitals through activities such as inspections, inspection reports, error reports, phone calls, and meetings. The regulator enforces extensive health care legislation and has the power to sanction at both individual and organisational levels. Informants at both the national and local regulatory level assess the legislation as powerful and satisfying for performing the regulatory tasks, ensuring quality and safety in health care.

[1] In addition to the Board of Health and the Chief County Medical Officer, the Directorate of Labour Inspection enforces legislation concerning health, safety, and environment for hospital employees.

Hospitals are obliged to report to the regulator both those errors causing serious patient injury and any serious near misses. All error reports are stored in a national database. The purpose of this mandatory reporting system is to clarify why errors and near misses occur and to prevent their reoccurrence. According to policy documents, the regulator should take an active part in vitalizing the hospital's obligation to report and to manage errors internally. The regulator expects the hospital's error management system to include an internal reporting system and an active use of these error reports within the hospital divisions. The hospital's quality committee should play an important role in this work. The committee is mandatory with a mandate concerning overall hospital quality and safety. In practice, the local-level inspectors are not satisfied with the hospital's internal error management system or the work of the quality committee:

> The internal error management system is vital to patient safety. It is mandatory, just like the obligation to report, and should act as a tool to increase quality and learn from errors. The reporting culture is one matter; all reports should not necessarily be addressed to us. The hospital has to select reports related to degree of severity and manage them in the quality committee. This means they should learn from their errors, but here they fail. That doesn't work within the hospital (local-level inspector).

Based on the severity of reported errors, the regulator can open cases against medical personnel at an individual level, or against the hospital at an organisational level. Medical personnel can thus be individually liable for errors reported by themselves or others. The local-level regulator collects information to evaluate whether someone is liable and should be sanctioned. The information collection mainly consists of written information such as journals and reports from the involved medical staff and departments. In cases of liability, the case is sent to the national-level regulator who holds the power to sanction. Informants within the regulator find the written information collection satisfactory for evaluating the cases, while informants within the hospital and the patient representative association are doubtful of this investigative practice, characterising it as too narrow and distant:

> They should be out there talking directly to the personnel, doing interviews to get rich information. Employees close to the accident often have the experience and knowledge that could contribute to better learning and understanding of the error. In addition, personnel indirectly involved in the error are not even asked for written information regarding the event. This results in mediocre error investigation, taking too long before the results are available. In the mean time dangerous routines go on (hospital employee).

The regulator performs two types of inspections: Planned system revisions (all hospitals yearly) and event-based inspections (reactive response to reported errors or suspicion of insufficient practice). The planned system revision involves document analysis, meetings, and interviews and results in an inspection report that documents deviations and demands for correction. In the regulator's opinion, Norwegian hospitals in general apply inspection reports only to a certain degree to improve safety at an organisational level:

> The hospitals are not learning organisations and it is quite unbelievable. It's like they're happy that they're neighbour departments are caught and not themselves. Instead we want

> the hospital as a whole to read the inspection reports and correct deviations often current in all departments. Today, we write good reports but we don't get the hospitals to read them (manager, national-level regulator).

In addition to enforcing the legislation, the regulator is supposed to give advice to the healthcare organisations to promote patient safety. Such activities are not predominant in the current study. Two regular meetings a year without a fixed agenda other than information exchange are held between regulator and hospital. Furthermore, the regulator does not seem to play an important role in the hospital's feedback and learning from errors. There was little knowledge of participation by regulators in knowledge transfer between hospitals or training activities to improve competence within error management. Several informants within the regulator see the advice part as important, since it involves dialogue and discussions without fixed answers, trying to encourage the hospital to find its own solutions. Despite this, the tendency during the last few years has been a clearer separation between the inspector role and the advice role. Informants are worried about mixing roles and becoming biased:

> It is obvious that it is difficult for us as a regulator to give advice and at the same time be a regulator, but we are supposed to do both. We can give advice in matters of internal control, juridical matters and patient rights. Usually, these advices are given in relation to an inspection (local-level inspector).

4.3 Hospital level

Healthcare reforms have changed the framework conditions for the case study hospital. According to the annual report from the local regulator, the hospital is underfinanced compared to other regional hospitals. In the period 2002 to 2004, the health region had operational budgets about 10% lower per inhabitant than the national average. This demanded that the hospital optimize production and increase efficiency and patient flow. The number of errors reported to the regulator during the last three years has indicated a falling tendency, resulting in an assumption of less safety focus at the hospital. Meetings between the local regulator and hospital managers were held, focusing on error reporting and learning from errors. Regulator representatives expressed their worries concerning obvious underreporting, since information from other channels (media, police, phone calls, complaints) indicated a higher number of factual errors than the hospital reported. One of the hospital top managers explained his view after the regulator-hospital meeting:

> Well, I have lived in a world believing we were quite good at error reporting. But the regulator claims there exists an underreporting. We must get this in order and communicate to the employees that they must report. The other thing they are preoccupied with is the learning loop on reported errors within the divisions and the quality committee. We haven't been especially preoccupied with managing errors within the quality committee, but I recognize that the regulator is, so we have to keep this in mind and get it in place (top manager, hospital).

At the hospital level, patient safety and quality improvement has been emphasized as an area of priority to promote patient safety as a competitive advantage:

> We focus on safety and quality. It's going to be our competitive advantage to get patients in the future. I believe patients will choose hospitals according to treatment survival rates (top manager, hospital).

Putting safety on the agenda has been perceived positively by the hospital employees, but specific results and activities are asked for. One example has been the introduction of an electronic error reporting system (EERS) that replaced the former written error reports. The former system was characterized by statistical exercises rather than learning processes. The intention behind the new EERS is to gather information and manage errors close to where they occur, to investigate active and latent errors, and to implement preventive measures. Informants characterized the new system as not properly implemented, with insufficient or no training. This resulted in a program of training "super users" within different parts of the organisation to spread knowledge of the system use. Further, the EERS was originally developed for the oil and gas business. Transferring it to the health care system without sufficient adjustments resulted in underreporting and frustration after the implementation:

> The EERS hasn't worked good enough and it is not made for our system. I know that for my division, and I believe it's current for all other divisions as well, it exists an underreporting of errors during the implementation phase. The system was "perfectly" introduced: here you've got it! Then the people involved disappeared, the training was not taken care of and we still struggle with it. You can't just throw a new system into the organisation. I haven't seen any training. We have super users, but this is established in theory and doesn't work in practice. Of course this worries me because I have insufficient knowledge of the errors in my division (division manager).

4.4 Managerial level

Changes in hospital financing and demands to reduce waiting lists have caused several changes at the managerial level, and the focus on economy, production and competition continuously influences decisions affecting the medical personnel. These changes are considered to have the potential to create a new set of emerging risks:

> It is one of the greatest challenges, I won't call it a risk, but it can turn out to be one. It's a challenge for us to deal with the yearly increase in patient volume, within the same buildings, and with no increase in total resources (HSE manager).

The organisational changes have been challenging and caused internal conflicts. The hospital management encourage all divisions to report errors and prioritize patient safety, yet simultaneously express the importance of cost savings and budget balance. This compound pressure causes conflicts and limited time to error reporting, follow-up, and feedback to the involved medical personnel. Department managers

refer to the pressure for budget balance and express feelings of powerlessness and worries about understaffing and corridor patients due to lack of space:

> …there is a higher focus on deviation from budget, than on deviation from safety…(middle manager).

In other words, the hospital organisation has limited resource slack (time, personnel, economy), and in practice, patient safety loses against budget balance. The hospital is organised to manage normal daily work operations, but has low reserve capacity to manage activities outside the short-term production perspective, such as error reporting, feedback, and training. These cross pressures are more present at the divisional and departmental level, since error management and the implementation of new routines and procedures to prevent errors are delegated to managers at these levels.

Different practices related to error management exist across divisions and departments. Results show a low degree of experience transfer concerning error management between divisions, and the quality committee that is formally responsible for this experience transfer is regarded as not fulfilling its obligation.

4.5 Staff level

Almost all informants at the staff level had experience with errors and believed errors occurred more often than were formally reported. Several types of errors were repetitive and not prevented, and the informants agreed that stress and work pressure had a negative impact on the error rate:

> I think there is a large number of errors, probably every day. An example of a repetitive error type is giving the wrong medication to the wrong patient (assistant physician).

Underreporting is a challenge within the hospital. Most informants believe underreporting exists, which is confirmed by numbers from a psychosocial environment survey carried out in 2004 (Holte et al., 2004). Its results showed that 10.8% never report, 6.6% seldom report, 17.2% sometimes report, 44.3% usually report and 21.2% always report errors.

Informants referred to an open culture for discussing errors, but said that such discussions usually were characterized by informal person-to-person communication. Near misses were even more seldom discussed. The openness for discussing errors was to a certain degree hampered by fear of a negative response to error reporting, such as a feeling of awkwardness, loss of reputation, or media coverage. The results also indicated that collegial cover-ups occurred, especially among physicians.

Practices for error reporting varied between occupational groups, as did the perception of what should be considered as reportable errors. Physicians were not especially preoccupied with error reporting, and they did not view errors as a precondition for learning. Among the nurses, there was more systematic training related to error reporting, resulting in a higher degree of reported errors:

> Nurses definitely report the most, partly because they have a lower threshold to do so, and partly because they are more aware of these things (physician).

The results of an analysis of written error reports within two hospital divisions show that nurses reported 65% of the total amount of errors. Compared to other occupational groups, physicians reported 4.6 %, auxiliary nurses 5.5 %, and bioengineers 9.5 %. Nurses are by far the largest occupational group at the hospital, so based on the numbers, one could not conclude that nurses commit errors more often than others. The difference between occupational groups is rather a result of different risk perception, different thresholds to report, and different reporting cultures. According to the informants, analysis and feedback on reported errors also varied, and learning from errors was sporadic.

> It would be better if we could see that error reports resulted in something, that it was used. For instance if someone outside the department participated at department meetings, analysed errors and deviations, and explained this to us (head nurse).

4.6 Work operation level

The nature of medical work implies that risk is continuously involved in the work operations. Patients arrive at hospitals with illnesses or physical injuries and thereby introduce risks that may complicate the work operations. This fact can cause difficulties when comparing safety in health care with other industries:

> Risk is in the nature of medicine because we cut in peoples' bodies. People arrive with dramatic stuff, serious illnesses that we are supposed to treat with surgery. That is a risk in itself. There is a grey zone where you must assess if surgery is beneficial or harmful to the patient. You are in focus, and the results of your professional assessments always appear after your actions. If you choose not to do surgery and the patient dies it might be blameworthy, and if you choose to do surgery and the patient dies it might be blameworthy as well. That is probably why we receive complaints, because expectations to the results are unrealistic (division manager).

To get a picture of the frequency, severity, and types of errors in medical work operations, the written error reports within two hospital divisions (approximately 500 employees in division A, 420 employees in division B) were analysed. During the years 2003 and 2004, 894 errors were reported at the two divisions, corresponding to 0.52 reports per employee in 2003 and 0.45 reports per employee in 2004. The reporting frequency was slightly higher within division A than within division B. Table 2 shows the distribution of reported errors related to degree of severity at the two hospital divisions.

	Division A		Division B	
Severity degree	2003	2004	2003	2004
Unnatural death	2	4	1	1
Considerable injury	15	17	5	3
Less serious personal injury	86	127	58	53
Incidents that could lead to injury	199	115	88	74
No severity degree registered	15	13	11	7

Table 2. Reported errors related to severity degree at two hospital divisions.

The table shows eight unnatural deaths at the two divisions during 2003 and 2004, and 40 considerable injuries. The following error types were identified on the basis of the 894 reported errors: Patient falls (66%), medication errors (16%), lack of patient identification (9%), complications (7%), infection (1%), and equipment damage (1%). Only minor differences were identified amongst the two hospital divisions regarding severity degree and error types. The substantial number of reported patient falls (66%) compared to other error types was explained by the harmlessness of the error type and the difficulty in preventing patients from falling.

5. Learning interfaces

In summary, the contextual descriptions of the health care risk management system have revealed that learning from errors is sporadic, individually based and occurs separately within the system levels, with limited knowledge transfer and activities between system levels (Department of Health, 2001; Donaldson et al., 2000; Edmondson, 2004). In the following section, we highlight some of the most striking learning conditions and interfaces in our study.

5.1 The effect of changes at the governmental level

The healthcare system's ability to prevent and learn from errors was negatively affected by reforms initiated at the governmental level. Structural reforms concerning hospital financing and institutional management altered important framework conditions at all system levels. The reforms resulted in a cross-pressure concerning production, efficiency and safety at hospital, management, staff and work operation levels. The effects were time pressure, stress, increased workload, and understaffing (Bone, 2002), with a negative impact on the learning conditions within and across system levels. Studies of the UK National Health Service (NHS) showed similar results, stating that, although the UK government has given clear messages that safety takes priority over other goals, this goal is simultaneously subverted by the inadequacy of funding provided for the NHS (West, 2000).

5.2 The regulator–hospital interface

The regulator-hospital interface has a formally stated purpose of ensuring safe healthcare delivery and preventing errors, but in practice, the regulatory level has limited impact on learning from errors at the hospital level. There is a limited degree of feedback from the regulator to the hospital, management, and staff levels in cases of error reports. The hospital applies inspection reports only to a certain degree as a means for learning across divisions and departments. We claim that the control focus within this interface, and the individual focus usually taken in investigation and reactions, hamper openness, discussion and reflection related to errors (Johnstone & Kanitsaki, 2005; Morath & Turnbull, 2005; Reason, 2000). Furthermore, the regulator-hospital interface is characterized to a large extent by written information exchange, such as error reports, inspection reports and investigations. From a learning perspective, this does not foster reflection on, or discussion of, the error prevention processes (Hansen et al., 1999; Wiig & Lindøe, 2007). The regulator expressed concerns regarding the combination of advice and regulation tasks, fearing a loss of reputation and trustworthiness. In this study, this resulted in a lack of experience transfer initiatives from the regulator, for instance from other hospitals in the region.

5.3 Error reports as an upward feedback system?

Ideally, error reporting systems should be viewed as learning mechanisms giving feedback on active and latent errors at the work operation level to all upward system levels in order to apply improvements and/or changes. Today, the error reporting system more or less focuses on statistics and is not systematically applied in feedback processes or proactive searches for new risk sources and prevention of errors across system levels (Kohn et al., 2000). The newly-introduced electronic error reporting system within the hospital is not yet working properly and causes frustration, underreporting and difficulties in learning from errors. Thus, errors, if reported and managed, only have an impact close to where they occurred, resulting in local corrections and new routines. Individuals may learn and adjust their practice, but the learning processes occur in a vacuum (Leape, 1994; 2005).

5.4 A multi-level individual focus

Our results indicate that a blame culture (Firth-Cozen, 2001; Johnstone & Kanitsaki, 2005; Mulcahy & Rosenthal, 1999; Reason, 2000) is still institutionalized in the Norwegian healthcare system. This promotes an individual focus in cases of medical error and causes learning difficulties within all system levels. According to legislation (governmental level), the ability to sanction at the individual level is much stronger than at the organisational level. Furthermore, investigation in cases of errors (regulatory level) is individually focused to a large extent, and there is an overweight of sanctions against individuals, compared to the organisational or system levels (Norwegian Board of Health, 2006). At the hospital level, error prevention work tasks are delegated to management and staff levels, distributing the responsibility to lower levels (Carthey et al., 2001). Additionally, media focus is

often related to the individual healthcare employee, contributing to their fear of media coverage and negative reactions. At the staff level, an open climate to talk about errors has a positive effect on learning processes, but is negatively influenced by collegial cover-ups and fears of negative reactions and bad reputations.

6. Conclusions

Our multi-level case study in Norwegian health care has shown that different system levels are dependent on each other in the process of error prevention. Healthcare reforms constitute framework conditions that complicate error management, and the blame culture characterising the healthcare system counteracts learning from errors. The systems for error prevention and learning from errors are fallible, due to imperfections at all levels. Fallible humans are prone to cultural aspects such as underreporting and occupational differences, organisational aspects such as workload and error reporting demands, and societal aspects such as healthcare reforms' demand for higher production and an individualistic control system.

6.1 Implications for health care

Our study has shown that the premises on which error prevention in the healthcare system are based, and the processes of importance for error prevention, are all top-down driven, accumulating expectations and strain towards the lower levels of the system (staff and work operation). To prevent errors in health care in the future, we believe that bottom-up structures and upward feedback mechanisms should be strengthened. Error preventive needs and constraints should be clarified at the work operation level and communicated to all upward levels for responses and measures. We recommend the following areas of priority:

- Performing safety impact studies prior to future healthcare reforms.
- Introducing person-to-person approaches in regulatory error investigations.
- Prioritizing the advice role within the regulatory level.
- Developing measures to counteract the focus on individuals relative to errors.
- Conducting searches for emerging risks and trends based on error reports.
- Developing measures to support and integrate electronic error reporting in work operations.

6.2 Further research

Further studies are needed to explore the multi-level error prevention system in health care. We suggest the following focal areas for future research:

- The study of knowledge brokers (Wenger, 1998) or the interface between clinical microsystems (Mohr et al., 2004) or communities of practice (Brown & Duguid, 1991; 2001) across different levels of the health care system.

- The study of informal or mindful learning practices (Weick, 2002; Aase et al., 2005) within single system levels to develop common learning features across levels.
- The study of conflicting goals or cross pressures between efficiency and safety (Bone, 2002; West, 2000), and the study of safety consequences as a result of changes at different system levels.

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Article II

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Risk regulation strategies in public emergency management - A learning perspective

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Abstract: The aim of this study is to explore how risk regulation strategies in public sector contribute to learning within emergency management. Strategies applied by the regulator entail diverse activities involving interaction and communication between regulator and regulatee. The paper explores learning aspects related to these activities. The paper is based on a multiple case study within Norwegian public sector including six municipalities and their belonging regulatory authority, responsible for regulating and inspecting municipal emergency management. The results showed that risk regulation through compliance strategies implied second order learning processes within the regulated. Risk regulation through deterrence strategies contributed to compliance with regulatory demands, but only implied first order learning process.

Key words: Emergency management, risk regulation strategies, learning, experience transfer, public sector

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1 Introduction

Regulation is a defining feature of modern society and can be viewed as centrally concerned with the control of risks (Hopkins & Hale, 2002; Hutter, 2001; Baldwin & Cave, 1999) and often imposed by the government on the behalf of the society. It is challenging for risk regulators to choose the appropriate enforcement strategies to target the optimal method of regulating risks. Regulators seek to gain compliance with the law not merely through formal enforcement and prosecution, but also by applying a host of informal techniques, including education, advice, persuasion, and negotiation (Baldwin & Cave, 1999).

Previous research on risk regulation conducted within both public and private sectors regarding specific safety areas often involved regimes holding strong legislation and sanctioning power, such as nuclear power, oil and gas, and biotechnology (Kirwan et al., 2002). Less research has been conducted on how the government regulates risk exposed to the local society in areas of limited legislation, such as natural hazards facing the public sector. The number and severity of natural disasters have increased in recent years, resulting in rapidly increasing unexpected expenditures for society (Newkirk, 2001; Kleindorfer & Kunreuther, 2000). It is important for local planners and government officials to understand such events if they hope to be able to prevent and respond to them effectively (Seiler, 1996; Balamir, 2002). Research has shown that, despite the increasing impact of emergencies and disasters, local governments in general invest limited resources in emergency management, although emergency management at the local level is vital for effective preparedness and response to undesired events within society (Newkirk, 2001).

This paper addresses how government, despite limited legislation, uses regulatory enforcement strategies to regulate risks exposed to municipalities. The aim of the study is to explore how risk regulation strategies in the public sector contribute to learning within emergency management in the regulated municipalities. The strategies applied by the regulator entail diverse activities involving interaction and communication between regulator and regulatee (Black, 1998). Regulatory activities are important aspects by which a system can learn and improve (Kirwan et al., 2002; Reason, 1997). Therefore, the paper applies a learning perspective of the regulatory enforcement debate and analyses the learning aspects of regulatory activities. The research questions are as follows:

- How do regulatory enforcement strategies impact learning processes within the regulated municipalities?
- What kinds of learning constraints can be identified in the regulator–regulatee interface obstructing learning processes within the regulated municipalities?

Although the regulatory enforcement strategies involve interaction and reflection between the regulator and the regulatee, this paper is delimited to address learning processes within the regulated municipalities, exploring how the regulatory activities

and interface constraints contribute or hamper learning processes within municipal emergency management.

1.1 Context

The structure of the Norwegian Governmental system includes several levels: the governmental level (the Norwegian Parliament, government, and ministries), regulators and associations (directorates and regulatory authorities at the national level), regional regulators (local level regulators), municipalities, and public organizations governed by the municipalities, such as public schools and nursing homes. The risk regulation regime studied in this paper covers the top four levels:

1 the governmental level—namely, the Ministry of Justice

2 the Directorate of Civil Protection and Emergency Planning (DCPEP)

3 the County Governor as the governments' chief representative constituting the regional regulatory authority

4 the municipal emergency management structure.

The current study focuses on the interface between the County Governor, hereafter referred to as the regulator, and the municipality as the regulatee.

The risks regulated within the regime are rooted within diverse risk sources that vary across municipalities; such risks are usually related to geographical and natural conditions causing natural hazards such as floods, avalanches, and rockslides, or to infrastructural and industrial conditions causing vulnerability within society, such as large traffic accidents, power outages, water supply failures, pollution, and fire. The municipality is not supposed to manage these risks, but instead adopt an overview of the local risk sources through risk and vulnerability analyses as well as apply strategies to deal with these in planning processes to prevent accidents stemming from insufficient planning and prepare for potential exposure to these risks (Nilsen, 2007).

In accordance with governmental expectations regarding emergency management, municipalities are expected to perform risk and vulnerability analyses, compose an emergency management plan, execute emergency exercises, develop an internal control system that ensures continuous work processes within emergency management, and incorporate this system into the local municipal plan processes. The regulator supervises that the municipal emergency management processes comply with these governmental expectations. Within this risk regulation regime, emergency management is based on the principles of responsibility, similarity, and subsidiary, meaning that the institution responsible for a sector in normal situations is also responsible during times of emergency; furthermore, an emergency situation should be managed at the lowest level possible within the governmental system (NOU,

2000:24). Therefore, municipalities have the primary responsibility for emergency management.

A vital aspect within this regime is the lack of statutory law behind the demands placed on municipal emergency management—only governmental expectations exist. The strongest sanctioning power for the regulator is to reject municipal plans without sufficient risk and vulnerability analyses required by law. For the regulator, this implies that inspectors must emphasize aspects other than command and control in enforcing the regulation. The regime is founded on a belief in dialogue and advice as vital aspects of the regulatory enforcement strategies to manage undesired events at the lowest level possible.

2 Theoretical approach

The theoretical framework of the paper is based on theories of regulatory enforcement strategies (e.g., Baldwin & Cave, 1999; Black, 2002, 1998; Hood et al., 2001) and theories of safety learning (e.g., Gherardi & Nicolini, 2000a, 2000b; Aase & Tjensvoll, 2003).

2.1 Regulatory enforcement strategies

The concept of risk regulation regime denotes the overall manner in which the state regulates risk in a particular policy domain. The term *regime* describes the complex institutional geography, rules, practice, and institution of ideas associated with the regulation of risk (Hood et al., 1999, 2001).

Enforcement is a challenging component of risk regulation, and regulators use diverse strategies in enforcing regulation (Baldwin & Cave, 1999; Hutter & Lloyd-Bostock, 1992). One of the debates in the regulation literature concerns the use of compliance versus deterrence approaches as strategies for applying legal standards. Compliance approaches represent an informal style of regulation emphasizing diplomacy, persuasion, and education rather than the routine application of sanctions to produce a compliance culture within the regulatee. The regime promoting compliance approaches is flexible and tolerant, and its regulators are discriminating and pragmatic in their application of the law. The basic goal is to achieve compliance without invoking the formal legal process. Meanwhile, deterrence approaches are based on penal responses to regulatory violations and rely heavily on penalties or punishment to prevent those regulated from breaking the rules (Hood et al., 2001; Baldwin & Cave, 1999; Braithwaite et al., 1987). A regime promoting deterrence approaches is excessively legalistic, involving a strict imposition of standards. Proponents of deterrence approaches tend to argue that compliance approaches imply relationships between regulators and regulatee through shared experiences, contacts, and staff exchanges or familiarity, making routine prosecution unthinkable. On the other hand, proponents of compliance approaches argue the deterrence approaches fail to identify the best ways to improve regulatee performance, causing resentment, hostility, and a lack of cooperation in those regulated (Baldwin & Cave, 1999).

Some researchers argue for a hybrid approach, referred to as responsive regulation; in short, this approach promotes compliance responses for those regulatees identified as poorly informed or morally concerned about the regulatory requirement, while deterrence approaches are promoted for regulatees who demonstrate themselves to be opportunistic and amoral. These proponents argue that the trick of successful regulation is to establish a synergy between punishment and persuasion (Baldwin & Cave, 1999; Ayres & Braithwaite, 1992).

2.2 Risk regulation as a learning process

The risk regulation process can be characterized as a process of problem solving and learning (Hopkins & Hale, 2002:6; Kirwan et al., 2002:258), forming a learning cycle involving legislators, regulators, and the regulated—and hopefully generating systemic improvements (Reason, 1997:187).

Learning within risk regulation can be studied according to how the regulator organizes and performs activities in the inter-organizational interaction with the regulated (Black, 2002, 1998; Gherardi & Nicolini, 2000a, 2000b). According to Hansen et al. (1999), organizations have diverse strategies for managing learning. They describe two different strategies: the codification strategy and the personalization strategy. The *codification strategy* implies that knowledge is stored in databases to which people have access, making the knowledge easily useable. Organizations codify knowledge in "people-to-document" approaches, where knowledge is made independent of the originator and reused in different purposes. Various learning activities relate to the people-to-document approach, such as formal documents or written documentation including reports on requirements, standards, procedures, and evaluations (Aase & Tjensvoll, 2003; Pedersen et al., 2004). On the other hand, the *personalization strategy* implies that knowledge is closely tied to its originator and shared through direct people-to-people approaches. Organizations applying the personalization strategy focus on dialogue to enable people to arrive at deeper insights by going back and forth on problems they need to solve. It is important for these organizations to build networks of people so that organizational members can share knowledge in various manners, such as over the telephone, by e-mail, or in face-to-face meetings (Hansen et al., 1999). Examples of learning activities related to people-to-people approaches include personal contacts, informal networks, meetings, forums, emergency exercises, tabletop exercises, and debriefings (Aase & Tjensvoll, 2003). In the regulation context, some regulatory enforcement strategies may emphasize activities according to people-to-people approaches, such as dialogue and guidance, where knowledge is closely tied to municipal emergency management staffs and spreads through personal contacts. Other regulatory enforcement strategies may emphasize learning activities according to people-to-document approaches, such as written information or inspection reports, where knowledge is kept independent of the municipal emergency management staff and reused.

Different levels of learning exist: zero, single-loop, double-loop, and triple-loop learning (Argyris & Schön, 1996). Zero learning means that no learning occurs; people fail to take in any new information. Single-loop (also denoted as first order)

learning occurs when people make simple adaptive responses. It is a routine, incremental, conservative process that serves to maintain stable relations and sustain existing rules. It is basically a process in which learners gain competence in a certain activity, routine, or technology. Double-loop learning (also denoted as second order) takes place when people see things in totally new ways. This learning is characterized by the search for and exploration of alternative routines, rules, technologies, purposes, and goals rather than merely learning how to perform present routines more efficiently. The highest learning level, triple-loop learning ("learning how to learn"), occurs when people create new ways of developing new structures of thought and action (Snell & Chak, 1998; Lant & Mezias, 1996).

Despite the different learning approaches, barriers may exist that hamper the regulatees' learning in emergency management. According to Aase and Tjensvoll (2003), a lack of priority regarding emergency management is a common barrier. Emergency management should be incorporated into ordinary work tasks; however, it is often supplementary to the daily work tasks, causing a priority problem. The lack of competence, lack of variation in emergency exercises, and time pressures are other barriers causing difficulties in the learning processes (Aase & Tjensvoll, 2003).

3 Methodological approach

The current paper is based on empirical data from a qualitative study carried out in 2003. The study is a multiple case study (Yin, 1994) that includes six municipalities in two Norwegian counties. A case is defined as a municipality along with the risk regulator responsible for supervising municipal emergency management.

In designing the study, frequent contact with respective regulators regarding case selection within the counties was crucial. The case municipalities varied across factors such as population, size, location, risk sources, number of emergency management employees, whether or not a severe accident had occurred within the municipality, and how regulators evaluated the plans and exercises regarding emergency management. Table 1 provides an overview of the six case municipalities according to these aspects.

Table 1. Contextual description of the six case municipalities.

Contextual aspects	*County 1 (15449 km²)*			*County 2 (7281 km²)*		
Case	*Case 1*	*Case 2*	*Case 3*	*Case 4*	*Case 5*	*Case 6*
Population	1200	7500	3800	75000	1700	12000
Location	In a fjord surrounded by high mountains	In a fjord surrounded by high mountains	A mix of coastline, fjords, rivers, and high mountains	Costal area, hosting a large city	Inland area	Inland area
Risk sources[2]	Avalanche, rockslide, tunnel risk, fire	Avalanche, rockslide, industrial waste, tunnel risk	Flood, tunnel risk	Infra-structural risk (road traffic, ferry transport), industrial waste	Water reservoir breakage, avalanche, rockslide	Railway accident, industrial waste
Severe accident experience	Yes	Yes	No	No	Yes	No
Plans and exercises[3]	Sufficient	Insufficient	Insufficient	Good	Good	Insufficient

The two counties varied in aspects such as the number of regulatees within the county and the number of inspectors. County 1 (Cases 1, 2, and 3) included 33 municipalities and 8 inspectors; County 2 (Cases 4, 5, and 6) included 15 municipalities and 3 inspectors.

Data collection was carried out using method triangulation that involved qualitative interviews, document analyses, and observations to gather rich data (Patton, 1990). The study included 12 qualitative interviews with municipal emergency management employees and regulatory inspectors as well as the observation of a planned system audit within one municipality. Documents such as municipal plans, risk and vulnerability analyses, crisis management plans, crisis information plans, and inspection reports were collected, analysed, and compared with the interview data. Furthermore, second order data were applied to gather rich information about emergency management processes across Norwegian

[2] Based on emergency management plans, risk and vulnerability analysis, and interview data.

[3] Based on inspection reports and conversations with regulatory inspectors in the case selection phase.

municipalities and regulatory authorities. For this purpose, annual municipal surveys (DSB, 2002; 2005), conducted by the Directorate for Civil Protection and Emergency Planning, were integrated into the current study. The second order data were applied particularly to describe frequency and method application related to emergency management exercises as well as how municipalities evaluated their performance and the benefits achieved with improved emergency management.

The interview guide included questions related to learning, risk perception, risk communication, and trust. These issues were included in order to conduct a broad exploration of how risks are identified and communicated by regulatory inspectors and municipal emergency managers (Rothstein, 2003; Jensen & Kleivan, 1999; Stern & Fineberg, 1996), how municipalities apply risk information for learning purposes (Nilsen & Olsen, 2004, 2007; Reason, 1997), and how the aspect of trust influences the activities between risk regulator and municipalities (Hawkins & Thomas, 1984). This paper focuses on data covering the learning aspect within the regulatory activities.

Data are categorized according to the regulatory enforcement strategies identified earlier—namely, compliance approaches and deterrence approaches (Baldwin & Cave, 1999; Ayres & Braithwaite, 1992).

4 Results

This study found similarities and differences in the regulatory enforcement strategies depending on geographical location, number of regulated municipalities, and population of the municipality. All aspects of enforcement strategies from both deterrence and compliance approaches were observed in the different cases. However, most emphasis fell to compliance approaches in both counties. A large number of regulatees and extensive geographical distances within the county caused difficulties in using personal contact and advice during interactions. Such difficulties appeared within County 1 (Cases 1, 2, and 3), which was twice the size in square kilometres and number of regulated municipalities as well as having a more prominent control aspect.

In municipalities with typical natural risks present and with previous accident experience (Cases 1, 2, and 5), working on emergency management was less dependent on the interaction with the regulator, compared to municipalities without natural risks present and no accident experience. Municipalities with accident experience did not necessarily comply with governmental expectations, but informants explained how they lived with natural risks; such experience provided them with competence in managing emergencies. In practice, preventive measures were usually implemented after an undesired event or accident.

The regulator, as an external driving force reminding and encouraging municipalities to comply with governmental expectations, provided an important reason for municipalities to prioritize emergency management issues. The municipalities' ability to learn and improve upon practices was closely related to interaction with the inspectors. Different regulatory enforcement strategies involved

different learning activities; the results will be presented according to compliance approaches and deterrence approaches.

4.1. Learning within compliance approaches

Several learning arenas existed in the regulator-regulatee interface, and inspectors and emergency managers interacted and communicated on a regular basis in meetings, courses, seminars, phone calls, etc. In meetings and seminars initiated by the regulator, emergency managers across the county met and discussed common challenges and risk sources facing their respective municipalities. The regulators' rationale for these meetings and seminars was, among others, to assemble emergency managers to build networks across municipalities and facilitate possible future collaboration. The network of municipal emergency managers was valuable in terms of informal contacts and distribution of emergency plans among the municipalities, but the active networking seemed dependent on activities initiated by the regulator. Results indicated several instances in which regulators, due to the lack of legislation, developed different innovative activities to increase municipal risk awareness, disseminate new knowledge, and develop municipal emergency management. For example, inspectors within County 2 visited almost every municipality in order to inform politicians and emergency management staffs about their responsibility to respond to governmental expectations and the regulators' ability to sanction non-compliance. Furthermore, the inspectors prepared presentations of worst-case scenario examples, such as houses struck by rockslides or buildings located in extreme avalanche- and rock slide-exposed areas. They presented these examples for the politicians treating area plans and plan permissions, with the purpose of illustrating the importance of conducting risk analyses and incorporating them into the planning processes. One municipal informant said:

> I think this is part of a process of increasing our awareness in emergency management. It affects our work, and the regulator is strongly involved and very good at communicating the message. The regulator also arranges meetings where representatives from several municipalities attend and get information about safety issues.

The inspectors considered themselves to be consultants and collaborators and were usually reluctant to adopt a strong control approach towards the municipalities. Performing the activities related to compliance approaches, the regulators used an informal bottom-up approach. Results provided several examples of activities in which inspectors cooperated and actively assisted in developing and improving the municipal emergency management. In one municipality (Case 6) with limited financial resources and experience with emergency management, an inspector participated in the entire process of developing the first municipal risk and vulnerability analysis. In this way, the regulator contributed knowledge and tried to influence the emergency managers' mindset. Most municipal informants were satisfied with the inspectors' advice, assistance, and cooperation in these emergency management improvement processes.

Inspectors within County 2 facilitated the municipalities by distributing emergency management tools and artefacts. More specifically, inspectors manufactured electronically based templates for municipal risk and vulnerability analysis. Based on guidelines developed by the DCPEP, the inspectors also prepared and distributed document templates for creating municipal emergency plans and maintaining internal control. The inspectors explained that the distribution of a simple checklist was the most popular tool among the municipalities; the checklist was a straightforward, simplified risk and vulnerability analysis that the municipalities could apply in specific cases of land use and tick off certain issues before returning the completed list to the regulator. However, the DCPEP did not approve of the distribution practice and criticized the inspectors in County 2. Despite this disapproval, the inspectors continued the distribution because, in practice, the tools and artefacts simplified and improved the municipal emergency management as well as reducing the burden, and municipal informants valued them as time and resource savers. One informant in a mid-sized municipality with limited financial resources (Case 6) said:

> I think the regulator is a resource in several ways. They give advice and guidance and to some extent they do the job for us, which is very useful for the municipality. They have capabilities that we do not possess.

None of the municipal informants were formally educated in emergency management. Only the most densely populated case municipality (Case 4) had a 20 percent emergency management position; in the other case municipalities, emergency management tasks were additional to everyday work tasks. Municipal informants and inspectors perceived the lack of formal education and emergency management positions as substantial barriers. All municipal informants explained how they learned by practicing their assigned emergency management tasks, by taking courses, and by completing emergency exercises. The regulator organized courses covering various topics to educate municipal emergency managers, and the municipal informants who had attended such courses expressed increased risk awareness and indicated that they had searched for new alternatives and solutions. One municipal informant said:

> I've recently participated in a course at the Emergency Planning College[4]. It was a course arranged by the regulator on municipal safety and vulnerability. It was designed for municipal emergency managers and several municipal representatives participated. The course made me realize the value of the risk and vulnerability analysis and what a useful tool that is in a planning context.

According to all municipal informants as well as results from the municipal surveys (DSB 2002, 2005), the emergency exercise was the most important learning activity

[3] A college administered by the Directorate of Civil Protection and Emergency Planning. It is used for different courses and learning activities for staffs at all levels within the studied risk regulation regime.

initiated by the regulator. On a national basis, 70 percent of all Norwegian municipalities had completed exercises in the two years prior to 2002; the numbers for 2005 indicated 95 percent had completed them in the four years prior. Through the exercises, municipalities tested emergency plans and management in practice, which contributed to gaining important experience in managing various emergency situations and provided an excellent opportunity for the evaluation and improvement of emergency plans. Different methods were utilized, but usually the exercises were based on role-plays (applied by 83 percent of participants in 2002), often in collaboration with a neighbouring municipality. One municipality exercised according to a scenario prepared by the regulator, while the neighbouring municipality observed the entire process. Municipalities could, to a certain extent, adjust scenarios according to relevant risks. The scenarios were perceived as realistic, increased the attention to relevant risks, and contributed to an improved understanding of the importance of emergency management. Other exercise methods were tabletops (applied by 15 percent in 2002) and full-scale exercises, but only 13 percent of all municipalities conducted full-scale exercises involving external emergency services, such as the police, fire brigade, and healthcare professionals. Usually the municipality's top administrative and political management participated, and the most common exercise elements were the distribution of roles and responsibilities, decision-making, and media- and information management. Through emergency exercises, the municipalities prepared for managing new situations, and 70 percent of those who participated reported that they made improvements regarding crisis information management, role clarity, and updated risk and vulnerability analysis (DSB, 2002). One informant explained how the regulator contributed to learning within emergency management:

> Their controls increase our attention, and their reports identify conditions for improvement, but it's definitively the emergency exercises that are most useful for us and there is a need to exercise once in a while.

Despite the assessment of informal regulatory activities as relevant and interesting, inspectors expressed concern regarding municipalities' priority of emergency activities. Although regulators encouraged the municipalities to participate, they had no means to force them to do so. Due to the lack of legislation, the voluntary aspect was vital in the interactions between regulator and municipality. The voluntary aspect could manifest itself in both positive and negative ways regarding compliance with governmental expectations. Positively, municipal staffs became involved in learning processes; negatively, the voluntary aspect made ignorant behaviours possible. Emergency management was sometimes given less priority than mandatory tasks. One inspector said:

> It is obvious that, when our demands are not legally established, these tasks are given less priority than mandatory tasks.

4.2 Learning within deterrence approaches

This section describes and analyses activities with a more formal and systematic character in the regulator-regulatee interface. These activities included a stronger control aspect than the compliance activities, but they cannot be characterized as deterrence approaches in a strict sense. Regulators imposed these activities on the municipalities, and sanctions were used to seek compliance and state examples with preventive purposes.

By orders from the government, the regulator inspected each municipality every fourth year conducting a system audit. The system audit involved several activities: pre-meeting, document review, interviews, verifications, post-meeting, and an inspection report. Usually, a pre-meeting prior to the actual inspection initiated the system audit to trigger processes within the municipalities, such as plan reviews. Before the inspection, inspectors reviewed documents, such as emergency plans and risk and vulnerability analyses, to assess their status and reveal deviations in the municipal emergency management. Inspectors were preoccupied with the quality of the written plans, and the inspection focused on how deeply rooted these plans were in the organization. The inspection included interviews with vital members of the municipal organization, such as the chairman, chief officer, emergency management staffs, the technical department manager, and the municipal physician. The purpose of the interviews was to reveal whether the emergency managers were familiar with their responsibilities, duties, and plans. Following the interviews, the inspectors gathered all the informants in a post-meeting to summarise and agree upon needs for improvement. Finally, the regulator prepared a written inspection report stating the regulatory demands, submitted the report, and required municipal response in the form of a schedule for compliance. Despite the requirement for a written response, no such response was guaranteed. One inspector said:

> Remember that this is not established by law. In fact, one of the municipalities in the county has proclaimed that it has no intention to comply with our demands. Such language is very uncommon for us.

The informants within this case municipality explained the rationale behind the resistance to respond to requirements as related to a difficult financial situation, low priority, low perceived risk of catastrophic accidents, close location to a large city hopefully capable of assisting them, and a belief in the internal municipal competence to manage emergency situations.

The learning aspect was not predominant in performing the inspection activities within the deterrence approaches. The purpose of the inspections was to be an eye-opener, forcing the municipalities to improve their documents and plans and comply with requirements in the inspection report. One inspector said:

> I think the inspection in itself is a verification of the state of the emergency management, but I don't think they learn anything from it. It's as if some are better liars than others. But in fact they don't have to lie, because usually we find the reality in their documents. What

> municipalities learn from are advice, meetings, courses, and emergency exercises in particular. In my opinion these activities keep up the emergency level.

A general finding was the positive view of the inspectors and their authoritative role in performing the formal control activities. According to the municipal informants, the inspectors were not preoccupied with revealing deviations, and they would rather engage in finding opportunities to develop emergency management and focus on important improvement areas. The regulator had the power to raise objections against municipal plans that could bring harm to society. The regulator used the opportunity to sanction in cases where emergency management considerations were poorly conducted or absent in municipal plans. Usually, municipalities exposed to sanctions complied with the demands by completing the necessary adaptations and corrections. For example, when one of the case municipalities (Case 1) received an objection concerning the overall municipal plan due to lack of emergency considerations, the municipality chose the easy way out. A municipal informant explained:

> We corrected it and got away with it. We wrote a short chapter and stated that we will consider societal safety and emergency management in all our work and especially in the land use planning. They approved it with some doubt.

5 Discussions

Data from the two counties have indicated how regulatory enforcement strategies have different impacts on learning processes among the regulatees and how different constraints affect the regulatees' learning ability.

To summarize, the regulator applied regulatory enforcement strategies with a strong emphasis on dialogue-based activities, characterized by informal conversations, advice, and discussions under conditions of openness and mutual trust. The regulators stressed a wide range of activities related to compliance enforcement approaches and not necessarily with a learning perspective in mind; nevertheless, the regulator provided a healthy learning climate. The compliance approaches contributed to defining the process of risk regulation as a learning process. However, the positive influence depended on priority and willingness to participate in the activities facilitated by the regulator (Black, 2002; Aase & Tjensvoll, 2003).

The deterrence approaches implied control activities focusing on compliance with demands (Baldwin & Cave, 1999). Objections and inspections often caused adjustments, corrections, and attempts to comply, but the control activities implied solutions that were short-term in nature and could not be characterized as learning processes.

5.1 Risk regulation as a learning process?

Municipal emergency management is not legally established. Nevertheless, municipalities, with some variation regarding effort and quality, perform these tasks. Norwegian cultural traits and social values characterizing the society as consensus-oriented, involving participatory approaches among employers, employees, and regulatory authorities (Karlsen & Lindøe, 2006; Lindøe & Hansen, 2000), may to some degree explain the municipal work effort and interest in participating in regulatory activities. Risk perception may be another explanatory factor—particularly for the variation aspect in work effort and quality (Slovic et al., 1985). Experience with incidents and accidents as well as living close to natural risk sources (Cases 1, 2, and 5) influenced how informants perceived risks, took responsibility and acted if something happened in the local community. Real accidents and incidents increased perceived risk, made people realize that accidents could strike any time, and revealed the need for working proactively. Still, the emergency management work showed signs of being reactive, as accidents were "needed" before preventive measures were implemented (Bourrier, 2002).

In most cases, inspectors believed in compliance through persuasion and education, viewing themselves as consultants and teachers who provided regulatees with information and knowledge (Kitamura, 2000). In organizing compliance approaches, the regulator emphasized discussion, reflection, and networking in the regulator-regulatee interface. Knowledge was closely related to the inspectors and emergency managers and spread through people-to-people approaches facilitated by the regulator (Hansen et al., 1999). Learning within the compliance approaches fostered a co-operative and open climate, promoted knowledge circulation, and generated knowledge through actions and reflections among individuals, groups and communities of emergency managers and inspectors (Aase & Tjensvoll, 2003; Gherardi & Nicolini, 2000a). Through the compliance approaches, emergency management was promoted as a social and participatory process, and the courses, seminars, meetings, and emergency exercises contributed to increased knowledge level and second order learning processes within the regulated municipalities (Black, 2002; Lant & Mezias, 1996). Emergency management processes developed from incremental all-out-efforts, often initiated by an inspection announcement, to processes in which municipal emergency managers searched for and explored new alternatives, such as checklists, risk and vulnerability analyses, and exercises to solve their challenges. However, the compliance activities turned out to be particularly vulnerable to negligence and the presence of enthusiasts in the municipal emergency organizations.

In particular, the emergency exercises promoted learning processes in several ways. Through the exercises, the municipal emergency management organization enlarged their action repertoire, managed new variables under controlled circumstances, and prepared for new emergency situations (Lonka & Wybo, 2005; Weick et al., 1999). During the exercises the emergency managers could reflect in action and gather feedback on their performance, while plans could be revised and improved upon. The exercises enabled vital members of the municipal organization to

understand emergency management in new ways, develop new communication and coordination skills, and learn by practicing (Snell & Chak, 1998; Argyris & Schön, 1996; Brown & Duguid, 1991). The occurrence of diverse emergency exercise methods and elements coupled with a strong participation record (95 percent in the four years prior to 2005) indicated that municipalities found this activity interesting and important. However, exercising under circumstances that mimic reality as closely as possible should be stressed due to the low percentage of municipalities (13 percent) applying full-scale exercises in collaboration with vital institutions involved in real emergency situations. The capacity to manage real situations and develop practical skills such as coordination and communication may be reduced when only conducting tabletops or role-plays, not involving external participants or media pressure. Improving preparedness and emergency management requires balancing and applying diverse types of exercises.

The regulator's distribution of emergency management tools and artefacts in County 2 was ambivalent from the learning perspective. The tools and artefacts were indeed helpful and facilitated the work processes, but the distribution practice also involved a potential counteraction to second order learning processes due to the reduced practical experience with conducting risk and vulnerability analyses and establishing internal control routines. The regulator should balance the roles of expert advisers and active performers of the municipal emergency management work tasks (Reiman & Norros, 2002). Providing municipalities with these tools could result from inspectors' increased focus on speeding up compliance with governmental expectations rather than on developing sound learning processes.

5.2 Learning constraints

Financial problems were present in several case municipalities, resulting in a lack of priority in emergency management. Inspectors tried to influence decision makers by informing politicians about their responsibilities (Vaughan, 1992), but the lack of emergency management positions as well as education and knowledge among municipal employees, in addition to the conflicting demands between emergency management and production, were identified as learning constraints in the interface (Aase & Tjensvoll, 2003). Furthermore, the geographical distances and decreasing number of inspectors within the regulatory authorities could potentially complicate regulator-regulatee interaction (Jensen & Kleivan, 1999) and cause insufficient learning environments due to restricted ability to regulatory enforcement using people-to-people approaches.

The control activities, related to the deterrence approaches, did not foster a healthy learning climate with openness, reflection, and networking in the interface to the same degree that the compliance activities did (Gherardi & Nicolini, 2000a, 2000b; Hansen et al., 1999). In fact, aspects of the control activities could to some extent constitute learning constraints in the interface. Formal written documents and written information exchange were important aspects in organizing these activities, and the inspectors were usually preoccupied with document quality, rather than process quality, which is vital to ensure learning processes. Activities such as

inspections and document reviews were action oriented with the purpose of forcing municipalities to establish and revise their plans, conduct risk and vulnerability analyses, and get area plans approved (Baldwin & Cave, 1999). The municipalities usually did not ignore or postpone meeting the regulatory demands, but the control activities searched for deviations from governmental expectations, and the municipal emergency managers became preoccupied with making minor adjustments and adaptations to comply with regulatory demands instead of seeking new alternatives or exploring new work procedures to cope with their challenges (Argyris & Schön, 1996; Lant & Mezias, 1996). These findings concur with the fundamental idea of the deterrence approach in enforcing regulation in which fear of sanctions should result in compliance (Braithwait et al., 1987); however, in terms of learning and improvement, the deterrence approach did not contribute to continuous improvement processes within the regulated municipalities.

6 Conclusions

This study has approached the regulatory enforcement debate by applying a learning perspective to different regulatory enforcement strategies. This paper has discussed how compliance approaches foster both first and second order learning processes within emergency management in the regulated municipalities, while the deterrence approaches are delimited to fostering first order learning processes.

Regulatory enforcement activities must often contend with reasons for non-compliance argued by those regulated, such as competing demands, financial circumstances, and time pressures. In practice, these are learning barriers obstructing regulatory enforcement strategies and emergency management improvement. To foster learning processes among regulatees, these learning barriers need to be addressed, and a statutory law would support the regulator in doing so. Furthermore, even if a statutory law were provided, the regulator should facilitate arenas in which regulatees can meet, encourage networking and collaboration, and promote emergency exercises to improve safe emergency practices. Municipalities usually face similar challenges and can save both time and resources in cooperating and taking advantage of each other's expertise in emergency management.

This study has emphasized learning processes among the regulated. Future studies should explore how the regulatory authorities and inspectors learn in the interface. Dialogue-based processes involving communication and feedback loops should be explored in order to map how regulators and inspectors learn and how they develop their competences, tools, and strategies as well as improve regulation in the long run.

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Article III

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Patient safety in the interface between hospital and risk regulator

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ABSTRACT: The paper explores how regulatory practice affects procedures and routines regarding patient safety in hospitals. The objective is to explore how systematic and incidental interaction activities between regulator and hospital contribute to patient safety. The paper is based on a multi-level case study within the Norwegian health care system. The study indicates that despite the increased patient safety awareness and efforts within the hospital, the regulatory activities as they are performed in practice do not have a substantial impact on patient safety improvement and learning from errors within the hospital

1 Introduction

1.1 Background

It is difficult to understand and explore the concept of safety without linkages to rules and regulations. They span the system levels from the regulatory rules in laws, through standards down to operating rules at the work place (Hale 2006). Consequently, patient safety, risk management and regulation are interrelated concepts (Palmer 1999). Safety is a dynamic property of the health care system (Cook & Rasmussen 2005). It does not reside in a person, device or department, but emerges from the processes and the interfaces in a socio-technical risk management system (Wiig & Aase 2006, Gherardi & Nicolini 2000, Rasmussen 2000). The system levels are: Government, regulators and associations, local regulator, hospital, medical department, staff, and work operation (Ale et al. 2006, Wears 2005, Rasmussen 2000). To improve patient safety an important research subject is to explore the interactions between the system levels and to make explicit the interfaces of their normal work systems, and the impact of decisions on the constraints and decisions criteria at the other system levels (Rasmussen 2000). In this perspective, safety oriented regulators and their styles and practices are components of the system affecting patient safety in the hospital – risk regulator interface (Wilpert 2006, Walshe 2003). These interface activities, is the subject explored in this paper.

Patient safety improvement requires organizational learning and knowledge transfer at the system level, which entails changes in organizational routines that cut across divisions, professions, and levels of hierarchy (Rivard et al. 2006, Dixon &

Shofer 2006). The interface between the regulator and the regulated is an essential feature for the health care system to learn and improve patient safety (Kirwan et al. 2002, Reason 1997). The issue of how to manage errors in the relationship between the regulator and the regulated is sensitive and can be drawn between the liability aspect and need for openness related to errors (Wilpert 2006). Regulatory agencies face difficulties of accomplishing a dual mission of rule enforcement and learning. Formal activities and enforcing regulation interfere with learning activities because incentives designed for rule enforcement affect collection and interpretation of important learning information (Kirwan et al. 2002, Tamuz 2001). Knowledge and research on how regulatory agencies balance their dual mission can contribute to improve patient safety by promoting effective incident reporting systems and fostering a learning environment in hospitals and other health care organizations (Tamuz 2001, Kohn et al. 2000).

1.2 Objective

The paper explores how regulatory strategies and practices affect procedures and routines regarding patient safety in hospitals. The main research question is: *How does the interface between hospital and risk regulator affect patient safety?* This is further elaborated by the research questions: 1) *How does systematic or incidental activities in the interface contribute to patient safety? and 2) Does an individual or a system focus in the interface have different effects on patient safety?*

2 Theoretical approach

2.1 System or individual models?

Previous research regarding system and individual models in error management has revealed a blame culture within the health care system. The individual health care worker, and not the system, is blamed for medical errors (Reason 2000, Mulcahy & Rosenthal 1999, Leape 1994). The individual focus has hampered the organizational learning, counteracted explorations of work processes causing a loss of rich information about the interaction of individuals, technical work, and organizational processes (Vincent 2006, Leape 1994). According to Reason et al. (2001) all organizations are prone to the "vulnerable system syndrome" (VSS). The VSS-syndrome is constituted by three interacting and self-perpetuating elements: Blaming the individuals, denying the existence of systemic error provoking weaknesses, and the blinkered pursuit of productive and financial indicators. Recognizing its symptoms and taking corrective action is a prerequisite for effective risk management and improved patient safety. A crucial step is to engage in double loop organizational learning that goes beyond the immediate unsafe actions, to question the core

assumptions about human fallibility, and to reveal and reform the organizational conditions that provoke it (Tucker & Edmondson 2003, Reason et al. 2001). Theoretically, there has been a shift from an individual oriented model of errors to a systemic approach to errors within the patient safety movement (Infante 2006). Human, organizational, and cultural factors are now viewed as important elements in patient safety work, but in practice research shows that the individual model is still a prominent cultural aspect within the health care system (Leape & Berwick 2005).

2.2 Systematic or incidental approaches?

The previous research regarding systematic and incidental approaches in regulating risks and improving safety is a vast body of literature on improvement of work processes, from the local work places to regulator control regimes. Parts of this literature cover organizational development with strong linkages to quality management systems at a micro level (French & Bell 1999; Logothesis 1992) while other parts cover risk management and regulations at a meso-level (Kirwan et al. 2002, Hood et al. 2001, Frick et al. 2000, Hood & Jones 1996). Hood et al (1999a, b, 2001) present a framework for comparing and understanding variations in risk regulation regimes (RRR). According to the RRR framework there is a set of components that all control systems contain. In this perspective regulatory practice consist of control activities to perform standard setting, information collection, and behavior modification (Hommen 2003). This trio of control components aligns with policy making, monitoring and enforcement involving different forms and varying emphasize on the activities within different risk regulation regimes (Hood et al. 2001, 1999a, b). A key factor in this literature is the underline of systematic use of these control components as opposed to an incidental approach to promote safety work.

3 Methodology

The research design is based on a multi-level (Rasmussen 2000) case study within the Norwegian health care system. Data is collected using method triangulation of interviews, observation and documents (Yin 1994, Quinn Patton 1990).

The study is conducted within two hospital divisions, hospital top management, the Chief Medical Officer, and the Norwegian Board of Health. A total of 49 qualitative interviews were conducted. The informants were hospital top management and division management (6), hospital staff (32), inspectors at national and local level regulator (9), and patient representative association (2).

The interfaces are studied through: Systematic and incidental regulatory activities (process dimension) and the regulator's system or individual focus (structure dimension) in performing these activities. Four types of systematic activities are

covered: 1) System audit, 2) Event based inspections, 3) A mandatory error reporting system, and 4) Error investigations. The systematic activities are diversely performed but are all characterized by formal procedures. In addition three types of incidental activities are covered: 5) Courses, 6) Meetings, and 7) Exchange of personal knowledge.

3.1 Context

In the Norwegian context the systematic approach to safety is embedded in the regulatory framework. The Health Care Supervisory Act (1984) requires all providers of health care services to establish internal control systems, to manage safety and errors. The enterprises and services should be planned for, performed, and maintained according to standards and regulations. Specialized health care institutions are furthermore required to establish a quality committee as part of the internal control system. The quality committee is supposed to be vital in the hospital internal error management, especially in cases of reportable medical errors and near misses. Hospitals are required to report medical errors causing serious patient injury, and serious near misses, to the regulator.

An independent patient representative association is established in each county. The purpose is quality improvement and advocating patient needs, interests, and legal rights towards the specialized health care services. The association notifies the regulator concerning conditions requiring regulatory response.

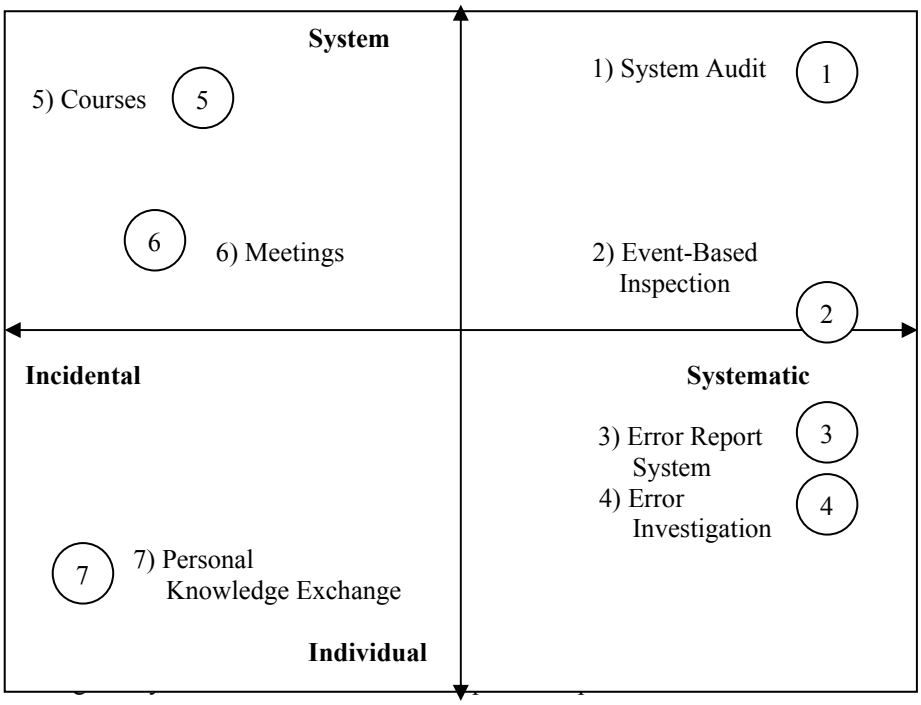
The Norwegian Board of Health is the regulator responsible for general supervision of health and social services at a national level. At a local level (county) this responsibility is delegated to the Chief County Medical Officer. Usually, the local level regulator interacts with the hospitals. Patient safety is an important work area for the regulator. According to policy documents patient interests, patient's legal rights, quality improvement, and patient safety are the main targets of the regulatory activities.

4 Results

The empirical material will be categorized and analysed according to two analytical dimensions: Process and structure.

4.1 Regulatory interface matrix

Figure 1 depicts how the regulatory activities covered in the study are categorized according to 1) Process (Systematic – Incidental) and 2) Structure (Individual – System). In Figure 1, the activities are categorized according to how the two dimensions are emphasized performing the regulatory activities in practice.



4.2 The process dimension of the regulatory practice

4.2.1 Systematic activities

There are two main types of systematic regulatory activities: System audit and event-based inspection. They are both inspections, but differ in numerous ways. Their characteristics are presented in table 1.

Table 1. Characteristics of system audit and event-based inspection

Characteristics	System audit	Event- based inspection
Approach	Proactive	Reactive
Information collection	Written and oral	Written
Document analysis	Yes	Yes
Meetings	Yes	No
Interviews	Yes	No
Written report	Published	Secret[5]
Verifications	Yes	No
Structure dimension	System	Individual/system
Process dimension	Systematic	Systematic

The system audit is delegated[6] from national to local level regulator. The local level inspectors have diverse opinions regarding the organizing of the system audit and its' contribution to improve patient safety processes. All local level inspectors believe the system audit initiate important patient safety processes within the hospital, such as document preparation, examination of internal control procedures, and increased awareness among employees. Performed within a specific medical domain or organizational level they consider the system audit to provide a proper foundation to assess the hospital's internal control system. The system audit results in an open inspection report, published by the national regulator. In the regulator's opinion, Norwegian hospitals in general only to a certain degree apply inspection reports to improve patient safety at an organizational level. Some inspectors question the efficiency of the system audit, and some are concerned with it's ability to map the hospital reality and actually reveal latent conditions threatening patient safety. The paper work can easily be checked, interviews can be performed, but to map whether patients receive proper treatment is difficult. A local level inspector explains:

> The system audit is variable in its function. We ask ourselves from time to time whether we apply our resources in an optimal way. I don't think we've found the perfect methods to perform our inspections. To get to the core of internal life within the hospital and find the exact level or existence of risks and vulnerability, is not easy for us.

[5] Open after a process of being patient anonymized.

[6] The legal authority for the national and local level regulator is stated in the Health Care Supervisory Act (1984). The local level regulators perform system audit according to local areas of priority; and nationwide system audits according to guidelines established by the national level regulator.

Informants at the managerial within the hospital are positive to the system audit and describe it as a well-organized process. They perceive the system audit as an aspect that improves patient safety and brings attention to internal error management processes. According to informants within the patient representative association, the regulator has an exaggerated confidence in the system audit, and the written documents analysed in the audits do not represent reality. The representatives stress the complexity within health care services and the complex risks caused by interactions, limited time resources, and high degree of information transfer within and across hospital departments. They doubt that the regulator is able to uncover such latent conditions by using system audits.

Opposed to the proactive system audit, the event-based inspection is reactive and more individually oriented. It is initiated by mandatory error reports, patient complaints, or by suspicion of insufficient practice. Based on the severity of the reported errors or complaints, the regulator opens cases against either an individual health care worker or the hospital. The regulator collects information and investigates whether or not the law has been violated and whether or not health services has been provided according to sound professional standards. In cases of liability, the case is forwarded to the national regulator who holds the power to sanction either the health care worker or the hospital. The hospital and the involved employees take the event-based inspection serious, and routines are improved locally, but improvements are not implemented hospital wide.

Current error investigation practice is based on formal written information collection of patient journals, reports from directly involved health care employees, and the hospital. Occasionally, expert judgements are used. Interviews are not part of the information collection. Informants within the regulator find the written information collection satisfactorily, while informants within the hospital and the patient representative association are sceptical to this investigation practice characterising it as too scant and distant from the hospital reality:

> They should be out there talking directly to the personnel, doing interviews to get rich information. Employees close to the accident often have the experience and knowledge that could contribute to better learning and understanding of the error. In addition, personnel indirectly involved in the error are not even asked for written information regarding the event. This results in mediocre error investigation, taking too long before the results are available. In the mean time dangerous routines still exist. (Hospital employee).

Some hospital informants and the patient representatives argue that error investigations should focus more on latent conditions, not just the active failures. The investigations could then contribute to change the focus from an individual perspective to a system perspective, and to a stronger degree reveal human, technological and organisational factors related to medical errors. The investigation is

further criticized for being time-consuming, and lack of feedback to the involved employees.

The regulator refers to a high degree of underreporting at the hospital, based on information from the media together with patient complaints. The inspectors are concerned with the current internal error management practice at the hospital, and have organized meetings with the hospital management to clarify legal demands and express their worries. The inspectors criticized the hospital quality committee, for lack of error management and the hospital for not analysing and learning from errors. A local level inspectors explains:

> Our responsibility regarding error reports is to control that the hospital's internal control system works. We assess if and how the error is managed at the department level and whether the quality committee has managed it. We are not satisfied with the present situation. In addition, the hospital strives to conduct a proper analysis and learn from the errors. Today, they just describe the error when we ask them to analyse it.

Informants within the hospital to a certain degree agree to the picture described by local level inspectors. Physicians and nurses admit that the error rate is higher than formally reported, and that they seldom or never report or discuss near misses. They usually perceive error reporting as statistics, involving limited feedback and influence on patient safety. The hospital management perceived underreporting as a minor problem before the regulator informed them. They admit that the mandatory quality committee does not hold a strong position within the hospital and is not working as expected. On the other hand the hospital emphasizes patient safety and quality improvement as one of five strategic areas. The hospital intends to promote patient safety as a competitive advantage in the future. Recently, the hospital has implemented a new electronic error reporting system, established a new patient safety position, and financed patient safety research projects to promote patient safety.

4.2.2 Incidental activities

Incidental regulatory activities are activities "standing on their own" and not part of a systematic and consistent "safety-control-system". These incidental activities are characterized by advice rather than control. All informants in the study are positive to the informal character of incidental activities, but the national and local level inspectors express a restrictive attitude towards advice. A national level inspector said:

> Speaking from a pedagogical point of view, we don't reject giving them advice, we rather give them hints of where they can find their answers.

Daily, the inspectors receive phone calls from health care employees asking for legal advice. Hospital informants express a low threshold to contact the regulator

informally. Twice a year, the regulator arranges a meeting for experience transfer between the regulator and the hospital. Meetings are also held incidental if necessary. There are examples of courses arranged by the regulator on request from the hospital in for example patients' rights. Informants report about a decrease in informal incidental activities the last years due to a sharper separation between the control and advice role caused by new legal reforms. The hospital informants consider the advice aspect as absent in the systematic regulatory activities, with exception of the system audit. In addition to enforcing a powerful legislation, the regulator is supposed to give advice to health care organizations, usually during inspections, to promote patient safety. A division manager expresses a general criticism of the overall regulatory practice:

> The advice role is more absent and I wish they were more advising than controlling, as the present practice is. The general criticism from health care employees is that the regulator emphasizes control. The regulatory practice is quite rigid and law-abiding and there is little room for considerations.

Despite the strong control orientation in the interface, all informants believe in the dialogue as a means to solve problems. The regulator expresses how trust and dialogue usually is preferred instead of sanctions, especially in cases where the hospital organization is the object for improvement and not the individual. There is a restriction within the regulator to apply their strongest sanctions at the system level. A national level inspector explains:

> We believe in dialogue. We seldom use our strongest sanctions at the system level. If we give an order to comply and they don't, well should we close down the hospital? So, we believe that if we don't exaggerate our use of the sanction abilities they know that when we reveal deviations we actually mean it. Usually that is enough to get them to comply with our demands.

4.3 The structure dimension of the regulatory practice

According to the regulator there has been a systematic improvement of the regulatory practice during ten to fifteen years. The regulator has developed the system audit to become a high-quality system-oriented method. Previous, the system audit was rule-based. A national level inspector says:

> It is our duty to assess reality against the law, but we must in a way test how this rule is complied with in a specific system. We assess what is justifiable treatment in a maternity ward, what do we expect there. I think we have become better to operationalize the rules in practice.

The challenge for the regulator is to incorporate the system perspective in the event-based inspection. Inspectors find themselves well competent to perform system level inspections (system audit), and to handle cases involving individual health care workers (event-based inspection). But they refer to a gap to bridge between these approaches, and there is an ongoing process at the national level to improve regulatory practice and move the event-based inspection in a more system orientated direction. A national level inspector said:

> We discuss how we can improve our regulatory practice and conduct system oriented inspections in cases of medical errors. Traditionally, the regulator has been preoccupied with the individuals when serious errors occur, and we have been unable to bridge these.

In a juridical perspective, the legislation is strong and states both duties and rights for the health care workers and the enterprises. According to the law, the individuals in the health care system are more exposed to diverse sanctions than the organizations. The patient representatives criticize the regulator for being weak in sanctioning the system level, and further that the criticism given from the regulator is not taken serious by the hospitals. Informants within the hospital management that usually interact with the regulator, argue that the regulator is careful sanctioning the individual and rather takes a system perspective. Hospital managers believe that physicians and nurses may have a higher perceived risk of reactions from the regulator because they are closer to the patients. The physicians and nurses express a fear of speaking up about medical error due to the possibility of negative reactions and sanctions. Inspectors at both national and local level admit their ability to sanction the individuals is much stronger than at the system level. But inspectors argue that the individuals sanctioned are in most cases sanctioned due to other reasons than individual medical errors. As a national level inspector explain:

> Just a few health care workers a year, lose their licences due to medical errors. But many are afraid of that so they hesitate to report themselves or others. We try to explain that there is another recipe to follow if they want to lose their licences. Our warnings are usually related to indefinite distribution of responsibility, bad communication, medication management and lousy journal record. If you avoid those four aspects, don't take drugs or have sex with a patient, well then you will not meet me.

The inspectors have a strong commitment to the distinct responsibility given by the law. For example regarding error investigations there is limited experience transfer from other relevant institutions. There is for instance limited communication with the Labour Inspection Authority about information regarding working hours and working environment that may be relevant for patient safety. Some local level inspectors argue in favour of a distinct responsibility between regulatory authorities:

> We focus on staff, but not on their working hours. The Labour Inspection Authority inspects that. We don't ask about it because we focus on the patient. We don't ask about subjects concerning the Working Environment Act, they do and they are preoccupied with long work shifts and understaffing. But it is obvious that if the workload is too high it is a threat to patient safety. But we don't inspect areas we are unable by law to inspect (Local level inspector).

5 Discussion

In our perspective, patient safety is a process dependant on learning and improvement across levels in the health care system (Rasmussen 2000). The study indicates that despite the increased patient safety awareness and efforts within the hospital, the regulatory interfaces as they are performed in practice do not have a substantial impact on patient safety improvement and learning from errors within the hospital (Walshe 1999, Brennan 1998). The case hospital has recently increased their patient safety efforts with a strong commitment from the top management. But the systematic patient safety activities required in the interface such as internal control activities, mandatory error reporting, and quality committee, suffer from a lack of priority and commitment from the hospital management and employees. The present regulatory activities are characterized by imposing corrective actions locally, rather than engaging the hospital in double loop organizational learning processes (Tucker & Edmondson 2003, Reason et al. 2001).

Ideally, risk regulators aim to be proactive, prevent and learn from errors, rather than reacting to them (Becker 2002). The present results focus on aspects of the systematic regulatory activities, except the system audit, that do not promote such learning processes and improvement (Walshe 1999). First, the present communication processes in the interface complicate learning because they usually come in the form of formal written information exchange, (letters, error reports, inspection reports and investigations). In a learning perspective, this does not encourage reflection and discussion within the hospital or across the hospital – regulator interface, and thereby both system levels suffer from learning disabilities (Wiig & Aase 2006, Høyrup 2004, Hansen et al, 1999). The incidental interface activities come in the form of advice involving informal person-to-person communication. These activities are not predominant in the interface, despite the positive attitude from the hospital regarding these activities. Second, the lack of feedback processes, reflection, and experience transfer in the regulatory activities cause an insufficient learning environment in the interface (Schulz 2005, Høyrup 2004, Svensson et al. 2004). Based on system audit and event-based inspections, errors are corrected at a local level. Practices and routines are changed locally, but new knowledge and practices are not properly diffused either within the hospital or across system levels (Wiig & Aase 2006). This implies that the hospital's internal error management system fails, and the regulatory practice faces difficulties coping with this fact. Third, a system perspective is

emerging, but as Figure 1 illustrates, only the system audit has a strong system focus in practice. The remaining three systematic interface activities event-based inspection, error reporting, and error investigation have a higher degree of individual focus, with a potential of counteracting exploration of working processes and prevent organizational learning (Reason et al. 2001). There is a paradox situated in the regulatory legal framework. The liability aspect within health care legislation has a potential influence patient safety improvement, the openness to speak up, and the error reporting within the hospital. The law on the one hand focuses on the system responsibility to provide safe health care, but at the other hand sanctions individuals. This explains why the regulator is restrictive sanctioning the system level, and why the employees have a higher perceived risk of being sanctioned (Leape 1994, Reason 2000).

There is a need to think of patient safety issues in terms of processes depending on the total system within health care (Ale et al, 2006, Wiig & Aase 2006, Wears 2005, Rasmussen 2000). The current limitation of an exclusive focus on single system levels such as the hospital or physicians must be transcended and considering a multitude of factors that are able to contribute to safety. Patient safety is an inter-organizational phenomenon and reference organizations, the patient representative association, and different regulatory authorities could be stronger involved promoting patient safety (Fahlbruch et al 2000). In the study the regulator seldom seeks relevant information from other regulatory authorities or patient representative associations. Such information could provide important information in the error investigation practice, and contribute to enhance knowledge about latent conditions and system factors causing medical errors (Walshe 2001). The hospital requires the regulator to provide advice and best practices from other hospitals, but the regulator's difficulties in balancing the different roles of control and advice complicate the error investigation process as well as learning from others (Reiman & Norros 2002). There is a need to reconsider current error investigation practices. The regulator already has realized there is a need for a stronger system oriented practice, and this aspect is presently changing (Infante 2006). To improve the error investigation approach the regulator should consider applying people-to-people approaches such as interviews an focus groups as methods for information collection rather than relying on written information solely (Hansen et al. 1999). The results also show a need for reinforced feedback mechanisms in the interface as means for improved patient safety.

6 Conclusion

The regulator is a vital institution within the health care system, and the hospital-regulator interface can be analyzed according to different perspectives. The hospital – regulator interface is complex and involves several regulatory activities. Some activities are systematic, while others are incidental. The activities vary regarding

their underlying models of error management. As shown in Figure 1 regulatory practices are system oriented and individual oriented.

The variety of systematic and incidental activities is positive and provides a good basis for patient safety improvement processes. The systematic process, system audit, improves patient safety locally, but strives to improve patient safety across intra-organizational borders. Other systematic processes, such as the event-based inspection, error reporting, and error investigation contribute to keep staffs aware of their responsibility when doing harm, but the activities have less impact on patient safety due to insufficient communication processes and lack of feedback mechanisms across the hospital-regulator interface and within the hospital. The incidental activities contribute to increase knowledge level among hospital staffs and contribute to a positive communicative climate, but these activities are not predominant in interface.

The regulatory activities holding a system perspective, such as system audit and courses, promote openness and dialogue, and affect patient safety more positively than the activities holding an individual perspective. The individual perspective characterizing the event-based inspections, error reporting and error investigations contributes to underreporting, fear of sanctions, and hamper openness, discussion, and experience transfer.

In a patient safety process perspective, the approaches within the interface need improvements to move the systematic regulatory activities (event-based inspection, error reporting, error investigation) towards a system perspective, and to emphasize incidental regulatory activities (courses, meetings) more strongly.

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Article IV

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Risk perception within different risk regulation regimes

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ABSTRACT: This paper examines risk perception among officials and employees within different risk regulation regimes. Risk regulation regimes are complex systems, including institutional arrangements, at different system levels, ranging from the governmental, regulatory, organizational, and management levels to street-level bureaucrats. Officials and employees at different levels of a given regime may perceive risk differently, developing divergent attitudes towards the regulation and demands for risk management. This discussion focuses on institutional and instrumental aspects of risk regulation regimes—namely, the context and backdrop of regulation—as well as the content involving the objectives and styles of regulation. The paper explores how these institutional and instrumental aspects shape risk perception among officials and employees within two highly different Norwegian public risk regulation regimes. The study design is a most dissimilar case study approach covering specialized healthcare and municipal emergency management.

The results identified diverging risk perceptions across regime levels within the two studied regimes, implying the amplification of certain risks and attenuation of others; this suggests that the potential exists for latent conditions not to be discovered, managed, or learned from. In order to improve risk regulation, detect signals, and prevent accidents from emerging, the role of risk amplification and attenuation should be acknowledged. Improved risk communication mechanisms are needed to foster experience transfers across structural levels, applying a system perspective. Furthermore, educational activities and learning arenas should be supported in promoting a common understanding among officials and employees of how risks emerge in complex regimes, thereby hopefully avoiding the misperception resulting from risk amplification and attenuation processes.

Keywords:
Emergency management, patient safety, risk perception, risk regulation.

1 Introduction

In today's society the role of the state as a regulator of risk and safety seems to have become more influential (1). Influenced by the new public management movement, public institutions and agencies have adopted risk management ideas and blueprints from the private sector. However, state agencies manage risk in considerably different ways. Institutional arrangements, public perception, and the nature of risks give rise to substantial differences in risk regulation regimes (2,3,4,5). Risk regulation regimes are complex systems that comprise multiple components subject to diverse pressures and have their own sub-cultures. Risk is perceived from different points of view, and

decisions about risk stem from diverse rationalities that have the potential to complicate and counteract processes of risk regulation and risk management (6,7).

In practice, officials and employees in different levels of a regime may understand risks differently (2,3,8), work within different discourses of risk (9), and demonstrate divergent attitudes towards the regulation and demands for risk management (2,3,8). As a result, tragic events have occurred due to the misperception of accident signals among officials and employees as well as shortcomings in the regulatory process (10). One of Britain's worst medical disasters, the Bristol Royal Infirmary tragedy (BRI), demonstrated that contrasting perceptions of risk reflected a tainted understanding of data among different parties within the risk regulation regime at various times over a period of eleven years (9). The BRI was entrapped in a period of blindness (11), where no functioning external agency existed to monitor the quality of clinical performance of the healthcare professionals or of the hospitals (12).

As risk perception varies across risk regulation regimes' participants and system levels, there is a need for research addressing forces or influencing factors to explain this variation. More attention should be focused on the role of risk perception within risk regulation regimes (8), researchers should explore the characteristics of the various regimes themselves—namely, the context of the regimes such as the types of risk, public attitudes, and organized interests as well as the content of the regimes such as the legislation, institutional structure, and regulatory styles facing the officials and employees within the different regimes (2). In this paper, we argue for the need to address these factors in order to understand how some risks are amplified while others attenuated. This paper aims to explore risk perception among officials and employees within risk regulation regimes in two highly different public sectors: specialized healthcare and public emergency management. More specifically, we will explore how risk regulation regimes along with context (type of risk, public preferences and attitudes, organized interests) and content (size, structure, style) shape the perception of risk among officials and employees. The research question is:

> How do contextual and content elements of risk regulation regimes shape risk perception among officials and employees within different regimes?

Risk regulation regimes that regulate business and privatized utilities have gained much attention in previous research. Less commonly discussed are the analogous processes of regulation within the public sector (13). This study explores risk perception in two public sector regimes relying on self-regulation. Self-regulation regimes can vary in their structure, enforcement, and rule type (14). In this study, healthcare and municipal emergency organizations are required to develop risk management systems and procedures to secure and monitor compliance to standards established by the state. The public organizations are expected to establish routines to deal with non-compliance while regulatory officials supervise these processes (15).

2 Theoretical approach

2.1 Risk Regulation Regime

Regulating and managing risk include processes of risk identification, assessment, monitoring, and evaluation of social interventions (2,16). An understanding of the space or interface in which the regulator and regulated meet is important to gain new knowledge and improve understanding of how to regulate and manage risk in modern societies (17,18). This space can be approached by applying the concept of risk regulation regimes as systems of interacting actors ranging from street-level bureaucrats to policy makers. This paper is based on the risk regulation regime (RRR) framework developed by Hood et al. (1999, 2001). The authors presented a method for comparing different regimes and their commonalities and differences in institutional risk profiles, thereby tracking the activities of risk regulation in different domains (2,3). The purpose of this framework is to map the systemic interactions and relationships among different parts of a regulatory system.

RRR incorporates a two-dimensional anatomy. The first dimension comprises the three components that form the basis of any control system: standard setting, information gathering, and behaviour modification. The second dimension comprises the regime's institutional and instrumental elements, categorized as regime context and regime content. The *regime context* refers to the backdrop or setting in which regulation occurs. Three contextual elements tend to be stressed the most: 1) type of risk, involving the inherent features of the risk or hazard; 2) public preferences and attitudes, meaning how the risk is viewed by the public—varying from anxiety to apathy—as well as whether or not the media interest is hot or cold; and 3) the nature of organized interest surrounding the risk domain, referring to who creates and is exposed to risk and the ways in which these players are organized. These three contextual elements, to some degree, overlap, but they encompass what is most commonly identified as the main features of the regime context.

Meanwhile, the *regime content* denotes the regulatory objectives, the manner in which regulatory responsibilities are organized, and operating styles of the regulator. The three basic elements of regime content are: 1) regime size, meaning how much regulation is brought to bear on any risk within a regime, the extent of risk toleration, and the scale of investment going into the regime; 2) regime structure, referring to how the regime is organized, what institutional arrangements are adopted, and whether the risk involves multiple overlapping systems of regulation; and 3) regime style, referring to the operating conventions and attitudes of those involved in the regulations as well as the formal and informal processes through which regulation occurs. The style element also includes whether regulation is rule-bound or discretionary and whether it is based on command-control approaches or compliance approaches. The six regime context and content elements are broad in character; disaggregating the elements could help highlight the variations in greater detail when comparing similar regimes (2,3).

2.2 Risk perception

Risk perception is based on how information on the risk source is communicated, the psychological mechanisms for processing uncertainty, and previous experiences of danger. People construct their own reality and assess risks according to their subjective perceptions (19,20). Various models have been developed to represent the relationship between perceptions, behaviours, and qualitative characteristics of hazards. Within the psychometric paradigm research demonstrates that perceived risk is affected by a lack of control, dread, catastrophic potential, fatal consequences, and inequitable distribution of risk and benefits; moreover, it is affected by whether or not hazards are unobservable, unknown, new, or delayed in their manifestation of damage. Risk perception research rooted in the psychometric paradigm contributes to providing insights into humans' individual processing of hazard information (21).

In a broader sense, the cognitive heuristics and biases that shape individuals' risk perceptions are themselves shaped by organizational and institutional contexts, processes, and decisions. In terms of risk regulation, rules and regulations are omnipresent, powerful, and unavoidable, imposing structure and procedure on a wide variety of organizational forms while stimulating the strategic actions of organizations. Strategic interaction occurs among regulators, managers, and employees; thus, the understanding of risk is drawn in different directions (22). The social amplification of risk is founded on the thesis that hazards interact with psychological, social, institutional, and cultural processes in ways that may increase or decrease the perception of risk and shape risk behaviour. The experience of risk is not just an experience of physical harm; it is also the result of a process by which individuals or groups learn to acquire or create interpretations of hazards (23,24,25). Hazardous events hold a signal value, which individuals and social groups may perceive differently. These signals are subject to transformations as they are filtered through others—e.g., mass media, groups of scientists, governmental agencies, and politicians. These processes imply that diverse hazards are given more or less attention due to the diverse understanding of signals among individuals and groups of people, causing an amplification or attenuation of risks (26).

Limited research exists on risk perception within risk regulation regimes. Rothstein (2003a) made an interesting contribution to social shaping of risk through case studies conducted within UK RRRs. According to Rothstein, complex RRRs are vulnerable to the phenomena denoted as "institutional attenuation", which refers to institutional processes that serve to reduce regulatory inspectors' perception or awareness of a risk and/or perception of the policy importance of associated regulations. Institutional attenuation could contribute to ineffective monitoring and enforcement within the regimes. Rothstein's work highlighted some institutional factors as contributors to reducing regulatory officials' risk perception and attention to regulations. Institutional attenuation was most likely to occur when officials were confronted with unfamiliar risks because inspectors traditionally give more attention to observable and tractable safety issues rather than chronic and complex issues. Furthermore, institutional fragmentation had a tendency to contribute to information distortion and control problems within the regimes as well as cause multiple regulatory sub-cultures, resulting in diverse responses to risk from those involved in policy making, monitoring, and enforcement. Such institutional attenuation effects

could contribute to regulatory neglect and serious failure in monitoring and enforcing risk regulation (8).

According to Hutter and Lloyd-Bostock (1992), inspectors' perceptions of risk contributed to developing diversity in their enforcement practice. Inspectors' individual accident experiences indicated a tendency to amplify effects on inspectors and their subsequent enforcement practices in the form of, for example, altering risk tolerance criteria of specific risks and some developed "hobby-horses", meaning they emphasized certain types of risks over others. The cumulative effects of accidents also amplified the inspectors' risk perception and influenced enforcement practice. During inspections, inspectors frequently talked about previous accidents, to both managers and the workforce within the regulatee. The amplification of risk was demonstrated as the inspectors' awareness of risk associated with frequently investigated accident types were fuller and more vivid to them; the attenuation of risk was demonstrated as inspectors' awareness of risks associated with rarely investigated accidents remained more vague and abstract. Inspectors emphasized risks about which they were most likely to be able to do something, which in turn related primarily to existing safety regulations. Generally speaking, inspectors find specific and clear regulations more enforceable than vague standards (27).

3 Methodology

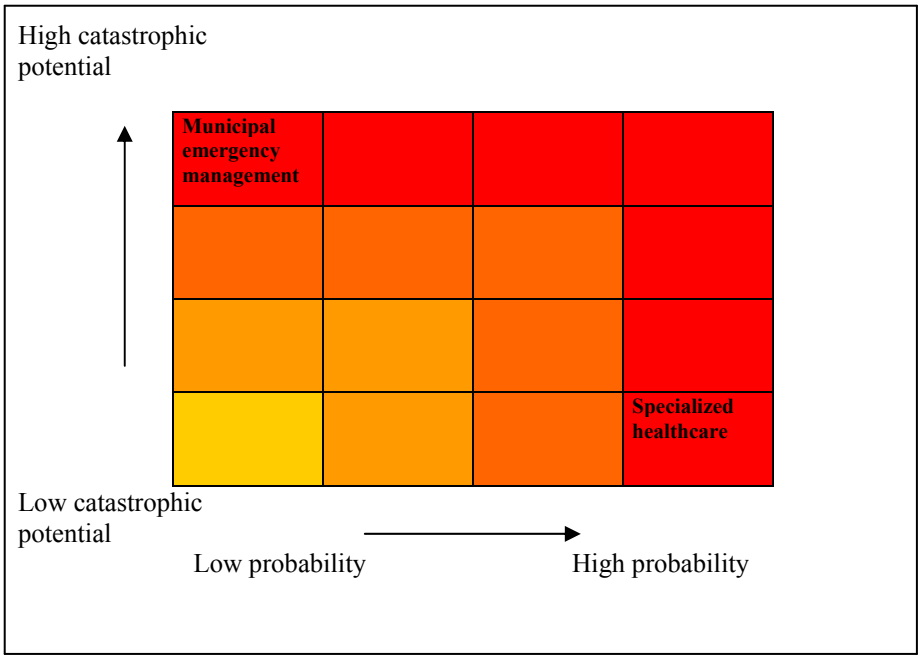
3.1 Research design and context

This study is a multiple case study of two dissimilar Norwegian public RRRs: specialized healthcare and municipal emergency management. The case study approach was chosen due to the characteristics and conditions of the regimes, which comprise multiple components, complex processes, and rapid changes. The case study approach is particularly applicable for gaining insight into, and understanding the structure of, a complex system and how its interdependent individuals, groups, and institutional components function (or fail to function) together (28,29,30,31). The study applies a most dissimilar case study approach (32) to generate contrasting data to explore how regime context and regime content shape risk perception among employees and officials within the regimes. The cases have been selected due to their diversity in instrumental and institutional aspects, such as type and scale of hazard, diverse formal rule specification, authority to sanction, history, enforcement strategies, and tools and practices used by the state. Such different cases allow the study of regimes with diverse balances between the regime content and regime context, thereby enhancing the analysis of the impact on how risk is perceived as well as mapping social and institutional factors affecting risk perception. Furthermore, the purpose of the design is to provide research material in which the contrasting elements enable the exploration of the interfaces among various parts of the regimes, such as between regulator and regulatee or among managerial levels within the regulatee. Regime interfaces are emphasized in order to explore their impact on risk perception among the officials and employees.

Society responds to different risks by developing different RRRs. The regimes covered in this study have different risk profiles. Within the specialized healthcare

field, medical error frequency is high, causing approximately 2000 patient deaths and 15000 severe injuries a year in Norwegian hospitals (33). However, the potential for catastrophe is low because medical errors harm one patient at a time (excluding epidemics and fires). However, in municipal emergency management, the risk profile is the opposite as various hazards are present; some represent a significant potential for catastrophe but have a low probability of occurrence. Figure 1 depicts the regimes in a risk matrix according to probability and consequence.

Figure 1: Risk matrix for specialized healthcare and municipal emergency management



Although public healthcare services involve both primary and specialized healthcare services, this study is concerned with specialized healthcare only. A case is defined as the hospital organization along with the regulatory authority responsible for supervising healthcare services—the Norwegian Board of Health at the national level and the Chief County Medical Officer at the local level. Both national and local level inspectors are included in the study.

The municipal sector is comprehensive and involves such areas as education as well as technical, economical, and social aspects. This study covers the emergency management carried out by the municipalities. A case is defined as a municipality along with the regulatory authority responsible for supervising municipal emergency management. The County Governor is the chief representative of the government in the county and, among several other responsibilities, supervises the municipal emergency management.

3.2 Data collection

Data were collected using a triangulation of qualitative and quantitative methods such as interviews, document analyses, observations, and statistical analyses (34,35). The application of methods varied within the different parts and levels of the regimes due to information needs, practicalities, and time constraints. An extensive methodological description and review of the single cases and data collection are provided in previous publications (36,37,38).

A total of forty-nine tape-recorded interviews were conducted within the specialized healthcare field using structured interview guides. Seventeen interviews focused on the relationship between the regulator and the regulatee (hospital), covering aspects of legislation, error reporting, learning, risk perception, and prevention according to inspectors, the patient ombudsman, and hospital management. Thirty-two interviews focused on how two hospital divisions managed errors, covering aspects of amount and error categorization, human and organizational factors, learning, power issues, and the regulator's role according to middle management, physicians, and nurses. Furthermore, we registered and analyzed a total of 894 written error reports from two hospital divisions using an Excel database. We analyzed healthcare legislation, Norwegian White Papers, guidelines and policy documents, inspection reports, and annual reports. The first author also observed a hospital-regulator meeting.

Within municipal emergency management, this study examined six case municipalities along with the regulatory authority in two counties. Frequent contact with respective regulators regarding case selection was crucial in designing the study. The case municipalities varied with regards to population, size, location, risk sources, size of emergency management staffs, occurrences of severe accidents, and how regulators evaluated the emergency plans and exercises. We conducted twelve tape-recorded interviews with municipal emergency management employees and regulatory inspectors, following an interview guide that included questions related to risk perception, risk communication, learning, and trust. Furthermore, the first author observed a planned system audit within one of the case municipalities to identify interactions between inspectors and emergency managers. We analyzed municipal plans, risk and vulnerability analyses, emergency management plans, crisis information plans, inspection reports, and annual reports. In addition, we applied second order data material from annual municipal surveys (39,40) regarding emergency management as well as an evaluation report (41) regarding the county governors' regulatory enforcement practices.

3.3 Data analysis

Qualitative data were analyzed by transcribing summaries and memos with relevant quotations from all data collection activities. The amount of interview data was extensive within the specialized healthcare field. To enhance the credibility of the qualitative analysis within this area, a multiple analyst approach (analyst triangulation) was used to independently review the comprehensive data material

(34,35). Quantitative data were analyzed using a statistical analysis of frequency with regard to error type, error severity, error causality, and personnel categories.

The total empirical material collected within both regimes was analyzed according to the RRR framework (2,3). We analyzed risk perception according to both regime context and regime content, applying the subcategories of each (type of risk, public preferences and attitudes, and organized interests for the former, and size, structure, and style for the latter) to identify their impact on risk perception among the employees and officials within the two regimes.

4 Two public risk regulation regimes

The following subsection presents the results from the two case studies separately. Case 1 describes municipal emergency management, and case 2 describes patient safety in specialized healthcare. The results from both cases are presented according to regime context and regime content.

4.1 Case 1: Municipal emergency management

4.1.1 Regime context

The study of municipal emergency management focused on perceived risk among officials and employees of both natural risk sources, such as avalanches, floods, and hurricanes, and technological risk sources, such as breaks in the water or electricity supply, conflagration, and infrastructural accidents. Several risk sources involve a catastrophic potential of harming inhabitants, environment, and vital societal functions. The threat against vital societal functions was an important feature of risks present within the regime, affecting risk perception among officials and municipal employees.

The presence of technological risks within a municipality increased employees' perceived risk; however, due to the seldom occurrence of and employees' limited experience with such technological breakdowns, employees were more preoccupied with familiar and frequently occurring situations such as natural risks or fires. Within several case municipalities, typical natural risks were present due to the geographic location in areas exposed to avalanches and floods. Three out of six case municipalities had experienced such accidents (37). Living close to the natural risk sources and experiencing accidents with fatal consequences caused municipal emergency managers to be more aware and conscientious of risk. Municipal emergency managers expressed concerns about the inhabitants and the municipal reputation in cases of emergency, which resulted in an increased work effort within emergency management through improved emergency plans and the implementation of risk-mitigating measures.

Inspectors were usually concerned with similar risk sources as employees, but they expressed more concern with the level of work effort within municipal emergency management. Therefore, the inspectors, through their regulatory activities, stressed the importance of continuous emergency management work processes in order to be prepared for all kinds of accidents and undesired events.

> There is a need for us to stress emergency management continuously or else they relax, and emphasize more urgent problems. Our guidance, meetings, courses, and emergency exercises are important to keep up the awareness within the municipal emergency management (inspector).

Public preference and attitudes coupled with organized interests, which overlapped in this sector, influenced risk perception to a certain degree among municipal emergency managers and inspectors. Although media coverage was limited on a daily basis, a higher frequency of natural accidents over the past years has resulted in an increased media interest, covering the responsibility and performance of municipal emergency management. The media interest increased municipal informants' risk awareness and led them to fear being exposed in similar situations. Municipal emergency managers expressed a strong commitment towards protecting local inhabitants from being exposed to risks caused by inappropriate land use planning, absent emergency plans, insufficient municipal responses in emergency situations, etc. A municipal informant explained the rationale behind the municipal emergency management work processes:

> The Norwegian Parliament has given municipalities the responsibility of emergency management. But the most important reason is expectations from other parties towards the municipal organization, expecting the municipality to be responsible and manage emergency situations. It would give inhabitants a bad impression if the municipality did not attend to the emergency management because, first of all, it results in insufficient solutions; second the municipality could be criticized; and last but not least, the inhabitants well-being is vital and consequences must be reduced if emergency situations occur (municipal emergency manager).

4.1.2 Regime content

The regulation within municipal emergency management does not entail comprehensive legislation, standards, or any extensive regulatory information collection or monitoring activities. The overall investment in the regime in the form of employment at the regulatory and municipal levels was limited and has been decreasing in past years due to structural changes at the regulatory level. The municipal emergency managers lacked formal competence within emergency management, and emergency management tasks went beyond their everyday work tasks. The regime incorporated no detailed act that required specific demands for municipal emergency management or supported the regulator through sanctioning. However, governmental entities expected the municipalities to conduct risk and vulnerability analyses, develop emergency management plans, perform emergency exercises, and develop internal control systems to ensure continuous emergency management processes in addition to incorporating these systems into local municipal plan processes. The regulator was supposed to ensure proper compliance to these expectations. According to inspectors and municipal participants, establishing a statutory emergency management act would contribute to increasing the emergency management awareness and effort. The absence of legislation, together with no previous accident experience, attenuated awareness and counteracted the non-

mandatory emergency management processes, leading the municipal emergency managers to instead prioritize their mandatory duties.

The regime structure was not perceived as complex by officials or employees; moreover, it did not complicate risk perception among officials and employees. The regime included the Ministry of Justice and the Police, the Directorate for Civil Protection and Emergency Planning (DCPEP), and the county governor supervising the municipalities. However, municipal land use planning overlapped municipal emergency management. The government expected risk and vulnerability analyses and emergency management planning to be integrated into both general municipal plan processes and land use plans in particular. The Norwegian land use act (Act-1985-06-14-77) provided the regulator with the legal authority to sanction non-compliance in the form of objections raised against municipal land use plans with insufficient risk assessments or when risks were assessed and accepted by the municipality, but disapproved of by the regulator. To some degree, the regulator applied the only available sanctioning means; usually the municipalities performed the necessary adjustments. The results herein also document scarce municipal budgets, with no positions dedicated specifically to emergency management. This caused difficulties in complying with governmental expectations and responding to regulatory objections due to a cross-pressure between legally established processes and emergency management in practice:

> A legal authority is necessary for municipal emergency management. I'm responsible for emergency management tasks and purchasing. It is difficult to combine these two tasks because new purchasing regulations recently came into force and I have to prioritize the work tasks as stated by law. That's how it works in practice, when different duties compete and you have limited time (municipal emergency manager).

Regulatory style and strategies were important factors in shaping the perception of risk among both officials and employees within municipal emergency management. Due to the lack of legal authority, the inspectors adopted regulatory styles emphasizing collaboration, personal communication, education, and persuasion in order to enhance the knowledge level among municipal emergency managers and initiate learning processes within and across municipalities in order to affect emergency managers' perception of emergency management as a useful process. In other words, the inspectors compensated for the absence of formal rules and regulations with a strong degree of interaction among the regulated municipalities to amplify risk perception, particularly among employees who lacked formal education and experience with emergency management. The inspectors emphasized learning activities in the interface between the regulator and the regulated (see 37) and arranged courses, conducted emergency exercises, and informed politicians to increase risk awareness among both municipal emergency managers and politicians. The inspectors and emergency managers all assessed the emergency exercises as the most valuable activity in the interface to promote common understanding of risk and learning within emergency management. Furthermore the DCPEP (superior to the county governor) distributed guidelines to municipalities regarding issues such as emergency planning, information preparedness, and risk analysis to inform, guide, and initiate emergency management processes.

The regulatory style was influenced by a shift in the definition of what constitutes common risks within the municipal emergency management regime. Ten to fifteen years ago, the regime emphasized emergencies during war more; currently, it emphasizes peacetime emergencies. This shift changed the interest among municipal participants in regards to viewing emergency management as relevant, useful, and related to undesired events that could actually happen in their local communities:

> The regulator used to be oriented against war. From our perspective, we were almost unable to understand what they talked about back then. But when they changed risk orientation away from thinking in war terms and started talking about floods, avalanches, and landslides, it caught our interest. They started talking about floods and avalanches in the areas with high concentrations of cabins, and we found it relevant because these are risks we have to manage in our municipality (municipal emergency manager).

Both inspectors and municipal informants perceived the imagination of war on Norwegian ground as unrealistic. Results showed that the shift in risk definition to a certain degree unified the inspectors' and municipal informants' understanding of risk, despite difficulties with priority, financing, and employment at the municipal level.

4.2 Case 2: Patient safety within specialized healthcare

4.2.1 Regime context

The types of risk studied in specialized healthcare focus on the perceived risk among officials and employees of harmed patients. Patient harm is related to medical errors such as misdiagnosis, mistreatment, medication error, and fall injuries. The healthcare system is complex, involving sophisticated technology, specialized professions, and tightly coupled interactions between employees and divisions in the hospital hierarchy, causing a complex and interconnected causality regarding medical errors. All such aspects affect risk perception in the healthcare regime. Risk perception varies according to officials' and employees' location within the regime (national or local regulator or within the hospital hierarchy), responsibility, profession, and personal experience with medical errors.

In the current study, participants at the hospital division and department level perceived increased risk due to conflicting demands between safety and efficiency, worrying about understaffing, corridor patients, and lack of time to perform tasks beyond everyday work operations, such as error reporting. All nurses and physicians revealed personal experiences with medical errors or those they observed colleagues making. They were preoccupied with specific risk types, such as medication error, prescription errors, and patient falls; according to the analysis of error reports, nurses and physicians often blamed themselves and not the system for such errors. Occupational differences also existed regarding risk perception; nurses were more aware of and paid more attention to medical errors than physicians did. Physicians to a stronger degree argued that medical errors and complications were inevitable parts of their profession that should be managed and discussed within the professional group, but not necessarily formally reported. Error classification was considered as

problematic both by nurses and physicians. They were confused about what to define as an error or a complication, whether or not they should report it, and how they should report it. Nurses reported errors more frequently than physicians. In general, an open culture for discussing errors existed, although some employees expressed concern regarding blame, cover-ups, trivialization, reprisals, and negative responses from colleagues and superiors if they admitted medical errors.

> I think negative responses may occur when people make mistakes, and you change your view of the person who made the mistake, particularly if the mistakes caused serious patient injury (head physician).

Communication about errors and near misses was usually informal through person-to-person conversations; however, patient safety issues and errors could be discussed in formal department meetings. Several employees and middle managers did not perceive information about medical errors and near misses to be relevant for other departments or divisions. Consequently, information lacked an upward communication path in the organization, which hampered information flow to higher organizational levels within the regime and reduced the ability to identify common problems, learn, and improve medical practices. Errors were corrected and learned from locally; however, similar risk sources across the hospital organization continued to injure patients repeatedly.

> The systematic safety approach is a challenge for the organization; errors are managed locally, but they are not incorporated into routines and procedures in a system, causing error reiteration (hospital top manager).

Participants within hospital top and division management and regulatory inspectors maintained an overall perspective on patient risk, worrying about system errors resulting from interaction and miscommunication among humans, organizational levels, and technology or in the interface between specialized and primary healthcare services. Although top management's perceptions of risk sources in many cases were in accordance with regulatory officials' perceptions, a large discrepancy occurred regarding perceived risk of underreporting. Inspectors explained that underreporting had increased during past years due to information being retrieved via informal channels. Hospital top management was surprised when inspectors confronted them with a presumed degree of underreporting.

Public preferences and attitudes coupled with organized interests affected risk perception within the healthcare case, particularly that which related to negative publicity. Sharp-end employees feared media coverage and were highly aware of the large media interest regarding medical errors. Medical errors were frequently covered in national newspapers and television, and the media often searched for scapegoats—usually the individual triggering the error. However, the hospital organization also experienced media coverage regarding the systems' responsibility to comply with formal safety regulations and internal error management routines and procedures. The national level regulator utilized the media to communicate safety issues in an effort to increase risk awareness among employees and managers within healthcare and assure the public of the regulators' role to guard public interests. The local level regulator

perceived the media as a partner, contributing information that occasionally resulted in cases being opened against individuals or institutions. Although a limited tradition exists for taking medical errors to court in Norway, the fear of negative publicity, in addition to the large public interest in increased perceived risk, hampered the ability of lower-level employees to speak up about or learn from errors. The government has improved patient rights in public healthcare, establishing a patient ombudsman and a national independent body to process compensation claims from harmed patients. As a result, public knowledge and awareness of these improved patient rights, together with the ability to claim financial compensation due to mistreatment, have increased, as have the numbers of claims[7] and payments[8].

> The public has become more offensive; there has been a change in attitude, and people are more aware of their ability to complain (local level regulator).

At the governmental level, patient safety interest has increased. The latest initiative was the establishment of a national patient safety centre to promote patient safety and learning from medical errors. In summary, patient safety and risks to hospitalization have become more present in the mind of the public, specialists, hospital managers, and regulatory inspectors over the past years.

4.2.2 Regime content

The regime structure involved a complex hierarchy that included the Ministry of Health and Care services as the owner of Norwegian hospitals as well as the Directorate of Health and Social Services, which is responsible for technical and certain administrative functions. Furthermore, the Norwegian Board of Health Supervision and the Chief County Medical Officer constitute the national and local level regulators responsible for supervising health services and healthcare personnel. Norwegian specialized healthcare services are organized in four regions; hospitals are subordinate to these regional structures. The hospital organization comprises several organizational levels, including top management, division management, department management, and physicians and nurses treating the patients. Ensuring safe patient care depends on processes across these levels of the regime. The current study demonstrated that the interconnected regime structure caused problems for employees, managers, and regulators in understanding the comprehensive processes essential for the provision of safe patient care. The structure complicated risk perception, risk communication, and feedback among regulators, hospital managers, and healthcare employees.

The regulator enforced strict and detailed regulations, involving several legal acts related to the rights and duties of the individual healthcare employees and the hospital organizations. A wide range of sanctioning means for both the individuals and organizations supported the regulator. Informants within different parts of the regime

[7] Total number of claimed cases during the past three years: 2004—2062, 2005—2671, 2006—3309.

[8] Total payment in million Euros per year during the past three years: 2004—50, 2005—55, 2006—60.

perceived the sanctions as being biased against blaming individuals due to more specific means being stated in the law against individuals than systems. Hospital physicians and nurses knew they could be sanctioned and, in the worst case, lose their licences; still, they usually did not worry about it. National and local level inspectors argued in favour of the system approach in patient safety and medical errors; however, they agreed that the regulator is presently supported with a stronger individual sanctioning repertoire.

> From a five-year perspective, our focus has changed towards the system approach, but we actually have a more extensive sanctioning repertoire against the individuals compared to institutions. The implication is probably that we are conceived as being better prepared for going after the individuals (national level regulator).

Currently, it is mandatory for hospitals to establish an internal control system to ensure high quality healthcare services and sound internal error management. Furthermore, hospitals must establish a hospital quality committee, with a specific mandate regarding error management in order to foster discussions and experience transfer across internal hospital borders. According to the law, hospitals are obliged to formally report all medical errors causing serious patient injury or serious near misses to the regulator; all error reports are stored in a national database.

These legislative elements illustrate the extensiveness of the legal framework to ensure patient safety. In practice, the findings showed a fallible error management system within the regime (36). A complex causality explained the imperfect system, in which perceived risk and benefit were contributing factors. The lack of perceived benefit for the employees to commit to the current error reporting system, time pressure, understaffing, and reluctance to discuss near misses caused underreporting, hampering information flow and learning activities. The quality committee did not comply with legal requirements due to low commitment to error management, almost absent experience transfer, and limited confidence and interest in their own mandate.

> The quality committee at the hospital level is a mandatory committee, and we must establish it. Well, the situation at our hospital is similar as within many other hospitals: we establish it because we have to. Our policy is to delegate problems connected with medical errors to the division level in order to ensure discussion about safety aspects closer to where problems occur (hospital top manager).

The local level inspectors and inspection reports express concern with low commitment towards internal control processes within the hospital. Inspectors perceived the present situation as unsatisfying, claiming the hospital failed to identify and learn from medical errors.

> The hospital does not perform systematic monitoring and revision of the internal control system to ensure its supposed function, in which the hospital has legal responsibility (inspection report, 2007).

For local level inspectors, it was sometimes difficult to get a proper overview of the complex hospital organization due to a limited workforce, recruitment problems, and information collection methods in need of improvement.

> I don't think we have good enough knowledge of the everyday life and the situations within the hospital. From time to time you get the feeling of powerlessness because we are few inspectors and we inspect large organizations and complex areas, and it is obvious that it is impossible to know the details. Therefore, it is important to use our time to reveal vulnerable processes or areas and contribute to improve patient care (local level inspector).

Some hospital participants as well as the patient ombudsman accused the regulator of overemphasizing formal written information collection and suggested supplying interviews to improve information richness in medical error investigations, for example.

The professional sub-cultures and specialized positions and processes in the hospital could increase risk and complicate risk perception and cooperation among employees. As physicians and nurses become specialists, they may develop a narrow perspective and not understand the importance of interaction within the regime. A local level inspector explained concerns about this issue:

> The physicians have 'procedure-mania' as I like to call it. They are extremely preoccupied with their specialities, and as specialists they think they need to improve their professional skills and knowledge. But in fact that doesn't contribute to safety improvements in a department; it could, in fact, become a patient risk if there are too many specialists because they live in their own world and don't know how to interact. Medical errors are not caused by a lack of professional competence; they are caused by a lack of interaction, a lack of a system perspective, and a lack of ability to communicate and incorporate all these components into the risk picture.

The regime style and strategies did not play an important role in shaping risk perception among officials and employees in the healthcare regime. A positive dialogue was evident between the inspectors and the hospital as well as a low threshold to contact each other; however, the interactions between regulator and regulatee were to a strong degree characterized by formal written information exchange. The regulatory practice emphasized control-based activities while advice, education, and persuasion aspects were not predominant in this regime (see 38 for a thorough discussion of the hospital–regulator interface). The study identified that the attention inspectors offered to certain risk types could affect the hospital's emphasis on error management. The most prominent example is patient falls, the category of medical errors most frequently reported within the hospital. This category has limited potential for severe patient injury exceeding fractures. Reported medical errors within two divisions from 2003 to 2004 indicated that patient falls accounted for a total of 65 percent of issues. However, neither the hospital nor the regulator directed any specific attention to this error category.

> We don't investigate patient falls. I cannot recall any of these patient fall cases being that interesting (local level inspector).

5 Discussion

Our studies within the specialized healthcare field and municipal emergency management have shown that risk perception differs among employees and officials within the various hierarchical levels of the risk regulation regimes (8,17). Risks are amplified and attenuated (23,24,26) throughout the hierarchical regime structures through risk management processes depending on interaction between humans, organizations, and regulators; external pressure from public and organized interests; and technological changes and financial circumstances causing compound pressure between safety and production.

The social amplification and attenuation of risks were more prominent in the complex specialized healthcare regime. One reason for this might be the exclusion of street-level participants in the municipal emergency management study. However, we argue that the most important reason is the differences between the two contrasting regimes, resulting in heterogeneous risk perceptions across the specialized healthcare regime and homogenous risk perceptions across the municipal emergency management regime.

5.1 Regime context and risk perception

Risk amplification and attenuation within specialized healthcare were influenced by the lack of consensus and lack of common conceptualization of risk across the regime (42,43,44). Risks were difficult to grasp for employees, hospital managers, and regulatory officials. Changes within the regime over recent years have implied a stronger professional specialization, with more specialized functions involved in patient treatment processes. This progress has in many ways improved the treatment while simultaneously creating a system vulnerable to patient handovers (45) and risk communication. The increased specialization implies a potential for information loss combined with restricted ability to track, evaluate, and learn from positive and negative patient outcomes. The increased specialization level may also explain nurses' and physicians' specialized and "narrow" perception of risk. Middle and top managers and, in particular, regulatory inspectors demonstrated a broader risk perception, explaining medical errors using a system perspective. Although limited financial resources and risk mitigation measures were incorporated into error management systems, the hospitals' top management showed increasing attention towards improving patient safety.

Our results are similar to findings from a case study of British Rail (17), in which Hutter (2001) demonstrated that occupational status and position within the risk regulation regime influenced employees' risk perception. Senior managers displayed a broader overview of risk issues, focusing on systems and general trends. For employees in the sharp end of the organization, concerns tended to be more specific; sometimes they were less likely to perceive the risk sources surrounding them. Several explanations relate to this issue; one is that employees in the upper corporate

hierarchy have more information available and thus a broader overview of risks. Moreover, understanding risk relates to employees' sense of autonomy and agency, and risk related to social status is reflected in adaptations to risk among employees who are the most exposed. As a result, risk could be normalized, even denied—seen as typical facts of life (17).

Regulatory officials espoused a system perspective towards error management; however, tacitly an individual blame culture still seemed to be institutionalized within the healthcare regime due to the unbalanced legislative sanctioning means against individuals and the employees' fear of speaking up (36). Furthermore, faulty communication caused misunderstanding, information loss, and ineffective feedback mechanisms (46,47,48), failing in the process of internalizing a system perspective across this regime. The current fundamental challenge of distributing risk information within the healthcare regime is affected by numerous barriers (49). The cultural, structural, and financial barriers (43,50) inherent in the regime, such as underreporting, the lack of error management commitment, the demand for higher production, and an individual control system, all contribute to a heterogeneous risk perception.

The various risk sources and characteristics with regards to probability and consequences were important in shaping officials' and employees' risk perception in both regimes. A majority of the nurses and physicians had experienced medical errors, but their reactions very much depended upon the outcome and their own personal sensibility (17). Several nurses and physicians were reluctant to discuss or formally report near misses if the events did not imply patient injury (44,51). Familiarity with risks in the sharp end could explain physicians' reluctance to error reporting (52) and their low commitment regarding the formal error management system (21,53). Complications during patient treatment were perceived as part of the medical profession; socially constructed mechanisms seemed to exist to enable individuals to cope with risks by normalising the risk sources and classifying them as complications discussed and managed within the professional group (17).

Within municipal emergency management, the familiarity with risk caused the opposite effect. The regime was not complex in terms of oversight, structure, or overlapping agencies; however, the risk sources could be diffuse and unknown. Municipal participants did not have experience with breakdowns in vital societal functions, and they did not particularly fear such events, despite the catastrophic potential. On the other hand, they feared the more familiar and frequently occurring risks, usually related to natural accidents. The fear of natural accidents and their characteristics as both highly probable and catastrophic for the local communities increased the perceived risk of being exposed and implied increased work effort (54). These findings align with previous research on flood risk perception that demonstrated that floods needed to be experienced, not only in magnitude, but also in frequency; without repeated experiences, the process whereby managers develop emergency measures of coping with floods did not occur (55). A similar example is the shift in orientation from emergencies during war towards everyday risk sources. Such change processes were caused by repeated natural accidents caused by floods and hurricanes, which led to insistent demands for national action. The accidents speeded up the legislative processes, but the changes were also a result of increased

public and organized interests influencing policy and decision-making processes within emergency management (Reports to the Parliament, 56,57).

Public preferences and attitudes as well as organized interests evident in both regimes contributed to the presence of reputation risk management, concerning how and whether certain events may be amplified or not by wider social processes such as the media and the legal system. These processes are uncontrollable for officials and managers and reflect a new sense of vulnerability to politicians and administration within risk regulation regimes (4,5,23,26). Within both regimes, participants were concerned about negative media publicity, and strived for a good reputation since both municipalities and hospitals were financially dependent of their inhabitants and patients. The reputation risk management aspects manifested differently at the various regime levels. Employees were concerned about their personal reputation and wanted to avoid media coverage, and hospitals and municipalities were concerned about organizational reputations; meanwhile, regulators wanted to demonstrate their supervisory role in guarding inhabitants' legal rights against hospitals and municipalities, utilizing the media for this purpose.

5.2 Regime content and risk perception

Our case study involving a most dissimilar approach demonstrated that differences in regime size, structure, and style are important in shaping risk perception. The regime size and its influence on risk perception can relate to the constitutive aspect of regulation, viewing regulation as part of a broader social "structuration" process. In other words, regulation structures relationships (17,22) and interfaces between system levels, which played an important role in determining risk perception in this study. Perception of risk was in part a social construct emerging from interactions among employees, professional groups, and regulators involved in the different regimes (22,58,59,60). Risks could also be "constructed" as common neglects (8), demonstrated by the patient falls attenuated within the entire healthcare regime. Furthermore, the legislative framework in the specialized healthcare field constituted the hospital error management system, but its practical application brought frustration, low commitment, and limited information richness. The error management system seemed trapped in a vicious circle because the understanding of risk could, in the next turn, be shaped by incorrect information leading to insufficient decision-making—and probably more frustration and even less commitment.

The complexity of regime structure serves as a key element in understanding differences in perceived risks within the different regimes (8). An interconnected, tightly coupled regime structure along with advanced technology and multidisciplinary employees in the healthcare case implied a loss of oversight. The complexity caused newly emerging interaction risks as perceived by the regulator that were difficult to observe for employees and correct within the hospital. Oversight and fewer organizational levels and operators involved in the processes, as in the case of the municipal emergency management, provided the employees and inspectors the ability to follow and understand the entire emergency management processes, from beginning to end.

The choice of regulatory styles is an important element not only for regulatory monitoring and compliance, but also for the inspectors' ability to affect employees'

risk perception. Within the specialized healthcare field, the regulator emphasized control activities and formal written information exchanges (38). Few arenas for dialogue existed (61), with the risk for misperceptions emerging across regime levels without proper arenas to clear up misunderstandings. Within municipal emergency management, the regulator compensated for the absence of legislation by emphasizing the regime style component and enforcement according to compliance strategies (61,62). By stressing a variety of arenas, emphasizing interaction and experience transfer, the regulator managed to increase the knowledge level, practical skills, risk awareness, and commitment to regulatory demands (37). In addition, this informal enforcement style contributed to more comprehensive, homogenous risk perceptions among officials and employees, beyond the specific risk types within each municipality.

6 Conclusion

This paper has explored how contextual and contentual elements of different risk regulation regimes shape risk perception among officials and employees. By using a methodology contrasting two dissimilar regimes, we revealed that differences in the balance between contextual (type of risk, public attitudes and preferences, and organized interests) and content elements (size, structure, and style) affect risk perception, resulting in amplification and attenuation of risk among different levels of risk regulation regimes.

- Contextual elements:
    - Risks imposed externally as observable risk sources were easier to perceive and manage, compared to risks emerging from interconnectedness followed by late manifestation. Internally emerging risks demonstrated a proneness to amplification and attenuation processes.
    - Public preferences and attitudes as well as organized interests implied risk reputation management with a potential of attenuation of certain risks.
- Content elements:
    - Size affected risk perception. The absence of legislation attenuated perceived risk among employees, while extensive legislation involving strong individual sanctioning means, applied strictly according to deterrence approaches, creates a proneness to amplification and attenuation of risk perception among inspectors and employees.
    - Structure involving increased complexity within the regime complicated the ability for officials and employees to make sense of risk, causing heterogonous risk perception across regime levels.
    - Style according to informal compliance approaches contributed to homogenous risk perception within the regime, while formal and more control-oriented enforcement styles involved the potential for complicating risk perception through amplification and attenuation processes.

The study revealed differences in the degree of heterogeneous versus homogenous risk perception across regime levels between specialized healthcare and municipal emergency management. We argue that the explanation for this variance lies in the differences between the two regimes. Although both regimes rely on self-regulation, a regime involving complex structures and formal regulatory enforcement of a detailed legislation will involve occupational and hierarchical variations in understanding risk. On the other hand, a regime with informal regulatory enforcement styles, limited legislation, and low complexity will imply less variation in risk perception. These content-related aspects alone do not shape risk perception; contextual aspects also have to be taken into account. Among contextual elements, type of risks was the most vital for shaping risk perception. Within municipal emergency management, risks were usually observable and therefore commonly conceptualized across the regime. Within the specialized healthcare field, some risks were observable and managed, but several risk types emerged due to the changes and complexity within the regime, turning out to be perceived differently across the regime—if perceived at all.

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Appendix I

Interview guide – municipal emergency management (municipality)

Introduction
- Purpose
- Use of data
- Anonymity

Background of the informant
- Education
- Previous work experience
- Present position
- Number of years in current position

Background information about the municipality
- Size
- Geographic locality
- Structure
- Economy
- Number of employees within municipal emergency management

Status of the municipal emergency management
- Risk and vulnerability analysis
- Emergency management plan
- Crisis information plan
- HSE – plan
- Emergency exercises

Characteristics of the municipal emergency management
- **Assessment of the competence and financial resources**
    - What kind of competence does the municipality have in municipal emergency management?
    - Is there a need for a different kind of competence?
    - How do you consider the financial priorities regarding municipal emergency management?

- **Assessment of overall goals within municipal emergency management**

  - How does the municipality identify risk and perform risk assessment?
  - Does the municipality use risk and vulnerability analysis in area plan processes?
  - How does the municipality incorporate risk into the overall municipal plan and area plans?
  - How does the municipality use the municipal emergency management plans in practice?
  - Why do you think the municipality conducts the municipal emergency management work tasks?

- **Participants in establishing risk and vulnerability analysis and municipal emergency management plans**
  - Who are the municipal participants in the establishing risk and vulnerability analysis and municipal emergency management plans?
  - Do any politicians or external stakeholder participate?
  - Do representatives from the regulator participate?

The regulator-regulatee interface

- How does the overall interaction with the regulator work?
- What happens when the regulator visit the municipality?
- What kind of contact/activities exist between the regulator and the municipality?
- Who are the employees with most frequent contact with the regulator?
- How is the dialogue between the municipality and the regulator?
- How do you assess the guidance from the regulator within municipal emergency management?
- How is the guidance performed?
- Does the regulator assist the municipality in order to improve weaknesses in the municipal emergency management?
- How do you assess the control aspects in the interface?
- How does the regulator focus on deviations from regulatory demands?
- What are your thoughts on the fact that municipal emergency management is not established by law? Should it be?
- How much work (in percentage of a full time position) do you think the governmental expectations require?
- What are your thoughts of the regulator?
- What kind of burden do diverse regulatory activities and demands constitute for the municipality?
- What do you think are the largest challenges for the regulator today?

Risk perception and risk sources

- What kinds of risk sources are present within the municipality?
- Could you tell me what kind of risks you perceive as the most prominent?
- Does the municipality have experience with accidents?

- If so, how did the municipality cope with it?
- How did the municipality work on municipal emergency management work tasks after the accident?
- Who influences what the municipality regards as risk sources?
- Which factors are important regarding the effort the municipality directs to the municipal emergency management?
- What kind of role does the regulator have regarding the perception of risk in the municipality?

Risk communication

- Are all municipal employees familiar with the risk sources and municipal emergency management plans?
- Does the municipal emergency management plan include industrial risk within the municipality?
- Is there any contact between the municipality and industry involving risk?
- How does the municipality communicate municipal emergency management plans to the citizens?

Trust

- How is the relationship between the inspectors and the municipal emergency management staff?
- Is the municipality open with regards to weaknesses in the municipal emergency management?
- How do you assess the emergency management competence among the inspectors?
- Do you think the regulatory tools and strategies are able to reveal latent conditions within the municipality?
- Are the everyday work situation and the demands from mandatory and voluntary work operations you experience in accordance with the view the regulator expresses about the municipality? (Compound pressure between resources and demands)

Learning

- How does the municipality evaluate the municipal emergency management subsequent to emergency exercises and undesired events?
- Does the municipality implement risk mitigation measures subsequent to emergency exercises and undesired events?
- Could you tell me if the municipality increases work within emergency management prior and subsequent to regulatory inspections? What happens?
- How does the municipality work within municipal emergency management in the period between inspections?
- Does the municipality do something special to keep a systematic attention towards municipal emergency management?

- How does the regulator contribute to the learning processes within the municipality?
- What kind of factors do you believe would improve the municipal emergency management within your municipality?

Appendix II

Interview guide – municipal emergency management (regulator)

Introduction

- Purpose
- Use of data
- Anonymity

Background of the informant

- Education
- Previous work experience
- Present position/responsibility
- Number of years in current position

Background information about the county

- Size
- Geographic locality
- Structure
- Economy
- Number of employees within regulator related to municipal emergency management
- Have you participated in inspections?

Views about the status of the municipal emergency management

- How do the municipalities emphasize municipal emergency management work tasks?
- Why do you think they perform the municipal emergency management work tasks?
- Does municipal emergency management usually satisfy regulatory demands?
- Do municipalities apply municipal emergency management plans as a tool in their ordinary management processes?
- What kind of benefits do you think the municipalities find in working on the municipal emergency management?
- How do you assess their emergency management competence?
- How does the regulator consider the link between municipal emergency management plans and the overall municipal plans?
- What do you think are the most important reasons that affect the municipalities' effort within municipal emergency management?
- What do you think are barriers within the municipal emergency management causing a reduced work effort?

The regulator-regulatee interface

- Could you describe the tools and strategies you employ?
- What happens when you inspect the municipalities?
- What kinds of documents are reviewed prior to the inspection?
- What are the main priorities when you perform a system audit?
- How do you provide feedback to the municipalities?
- What happens in the aftermath of the inspection? Does any kind of follow-up activities exist?
- What kinds of means are available in order to sanction non-compliance?
- What kind of activities and contacts exist between the regulator and the municipalities?
- Could you describe the degree to which you find the contact and activities satisfying?
- Is it the regulatory inspectors or the municipal emergency managers that usually initiate contact in the interface?
- How is the usual information flow? Written information exchange, telephone, e-mail, formal meetings, or informal meetings?
- How would you characterize the dialogue between the regulator and the municipalities?
- In what kind of occasions does the regulator have a dialogue with the municipalities?
- How does the regulator perform guidance within municipal emergency management?
- How does the regulator perform control activities?
- How would you characterize the role of the regulator within municipal emergency management?
- How do you assess present regulatory practice?

Risk perception and communication?

- What is the regulator's strategy in order to make the municipalities perceive and manage new risks?
- Does the regulator have any effect on how the municipalities perceive and manage risk?
- How do you think the regulator effect the work effort and attention to emergency management work processes within the municipalities?
- Is the regulator familiar with if there is any contact between the municipality and industry involving risk, located in the municipalities?
- How do the municipalities communicate risk to the citizens?

Trust

- How does the regulator work to grow trust in the interface?
- Does the regulator have trust in emergency management competence level within the municipalities?

- How does the regulator assess the municipalities' ability to comply with regulatory demands?
- How does the regulator vary the response to the single municipalities? Does variation occur? When?
- Does the regulator apply the same regulatory practice regarding small, middle sized and large municipalities varying in type of risk and number of employees?
- Do you think the regulator is able to see the correct picture of the municipal everyday situation?
- Do you think the regulatory tools are able to grasp latent conditions within the municipalities?
- How would you characterize the advantages and disadvantages concerning the regulatory tools?

Learning

- How would you characterize the ordinary municipal emergency management?
- Do you think the municipalities' work effort increases prior to and after control activities?
- Does the regulator do anything in particular to keep continuous municipal emergency management awareness within the municipalities?
- How do you think the regulator influences the learning processes within the municipalities?
- What kinds of factors do you think would improve municipal emergency management?

Appendix III

Interview guide – specialized healthcare (national regulator)

Background of the informant

- Position
- Previous experience

Responsibility and legislation

- Could you describe your work and responsibility?
- What are the legal acts most important for the Norwegian Board of Heath Supervision?
- How do you assess the legislation in order to secure safety and quality in patient treatment?

Risk areas

- What is your perception of risk sources or areas involving high risk within healthcare?
- What kind of errors do you think are most common?
- How does the regulator expect the hospitals to map and assess risks?
- Do you think there is a common perception of risk areas within the national level regulator, local level regulator, and the hospital? What kinds of discrepancies exist?
- In what way does a divergent risk perception between system levels affect your way of approaching the local level regulator and the hospitals? (Contact, attention, ways of interaction)

Regulatory tools and regulatory practice

- What is your overall regulatory strategy?
- How does it work? What is the objective?
- How do you assess the methods used in regulatory practice according to patient safety?
- What is the advantages and disadvantages and why? (System audit, event-based inspection).
- How does the national level regulator think about activities in the local-level regulator - hospital interface? (What kind of activities are acceptable, what type of contact, meetings, role performance and role conflicts?)
- Are you familiar with the §2 in the Health Care Supervisory Act (1984) stating that the regulator should provide guidance and advice in connection with performing inspection activities?

- How do you plan and conduct such guidance and advice activities in connection with inspections and not as a part of inspection?
- How could this aspect be improved?

Leaning

- The concept of a learning organization is often used in healthcare. What does learning organization mean to the national level regulator?
- Who is supposed to be a learning organization? The entire system, the regulator, the hospitals?
- How could learning processes be facilitated?
- How does the mandatory error reports system contribute to learning processes within healthcare?
- How do the healthcare staff and hospital receive feedback on reported errors from the regulator?
- How does the national level regulator evaluate the way hospitals manage error and use this information in order to improve patient safety practice?
- How does the hospital quality committee presently contribute to learning from errors and undesired events?

Proactive risk management

- How does the national level regulator conceive the hospitals' effort to prevent medical error?
- Has there been a change in the past years? Why?
- How can the national level regulator contribute to improved proactive risk management within the hospitals?
- How do you think activities between the local level regulator and the hospital improve patient safety?
- What factors do you think are the most important in order to improve patient safety in the Norwegian healthcare?
- How is the process going on a new national mandatory error reporting system? What is new? What will happen in the future?

Appendix IV

Interview guide – specialized healthcare (local level regulator)

Background of the informant

- Position
- Experience
- Number of years in current position
- Description of current work responsibility

Legislation, risk, report system

- Could you describe what you think are common types of risk sources in hospitals?
- Which risk sources do you think are most prominent and involve the highest patient risk?
- How often do you think medical errors occur? (Patient deaths, severe injury, minor injury, near misses)
- What type of risks obtains most attention in order to be prevented? (The severe seldom occurring/ minor often occurring)
- How does the type of risk and number of events affect the regulator's contact with the hospital?
- What are the legally established responsibilities for hospitals within patient safety?
- How are the institutions informed about this responsibility?
- Could you tell me about the regulator's responsibilities and duties towards the hospital?
- What is the regulatory demand in order for hospitals to establish an internal error report system?
- How do you think the error report system affects patient safety?
- How does the mandatory error report system work?
- What is the procedure for mandatory error reporting and feedback?
- Does the regulator facilitate any kind of training or education regarding error reporting? (why/why not)
- What does the regulator expect the hospital to do after medical errors have occurred, in order to learn from these?
- How does the regulator investigate medical errors? What is the purpose? How do you collect information? What happens? What kinds of measures are implemented?
- How does the regulator consider the role of the hospital quality committee within patient safety? How should it be?

The regulator - regulatee interface, tools, activities, roles

- How frequent is the contact between the regulator and the hospital?
- How would you characterize the contact and how is it usually performed? (Person-to-person, written, e-mail, telephone, meetings, inspections, reports etc.)
- Could you describe different approaches the regulator applies in the regulator-regulatee interface? Please give examples. (Dialogue, guidance, control activities, system audit, event-based inspection)
- How do you use these different tools/methods?
- How do you think your methods reveal latent conditions and weaknesses within the hospital organization?
- What is the purpose of the inspection reports?
- How do you think inspection reports are applied to improve patient safety?
- Could you describe your different roles as inspector? (Expert, consultant, authority)
- How can these different roles influence patient safety effort within the hospital?
- Does the regulator facilitate arenas such as courses, training, exercises, etc. to increase competence within patient safety issues? (If so, how does it occur and to what extent?)
- Could you tell me to what degree you consider that the regulator operates in a proactive or reactive way?
- Could you tell me about ways of sanctioning and how these prevent the recurrence of medical errors?
- How does the regulator stimulate the hospital to seek new solutions to manage risk?
- Could you exemplify specific risk mitigation measures the hospital has implemented to improve the patient safety level?

Leaning/experience transfer

- Are you familiar with arenas for experience transfer within the hospital?
- Are you familiar with any arenas for experience transfer between the hospital and the regulator?
- How do these work and what kind of information is transferred?
- What kind of activities contributes to experience transfer in the hospital-regulator interface?
- What kinds of barriers hamper experience transfer?
- What do you think are important factors in patient safety learning processes?

Competence, organizational size, resources, media publicity

- How would you characterize the regulator's oversight regarding the hospital? (The hospital ordinary work situation, pressures etc.)
- How does the size of the regulated organization affect your oversight?
- How would you characterize the regulator's resource situation? (Time, money, staff)

- How would you characterize the resource situation within the hospital?
- Do you think the resource situation is sufficient to establish an acceptable level of patient safety?
- To what degree would you say that the regulator holds a sufficient competence in patient safety issues?
- How would you describe the patient safety competence within the hospital in order to be able to perform proactive risk management?
- How does media publicity affect patient safety? (From the regulator's point of view, within the hospital and the healthcare employees)
- How do you think external stakeholders and political attention affect patient safety? (Within the hospital, between the hospital and regulator, within the regulator)

Appendix V

Interview guide – specialized healthcare (hospital top management and division management)

Background of the informant

- Education
- Position
- Experience

Responsibility, legislation, risk

- Could you describe your responsibility and your work?
- Could you mention the legal acts most important to patient safety and quality? (Directed towards the individual and organizational level)
- Could you describe what you think are common types of risk sources within the hospital?
- How often do you think medical errors occur? (Patient deaths, severe injury, minor injury, near misses)
- Do you know what type of errors are most common?
- How does the hospital map and analyze risk?
- Is there a common conceptualization of medical error between the hospital and the regulator?
- In cases of discrepancy, how does it affect the hospital – regulator interface? (Methods, attention, contact)

Error report system, learning

- What kind of regulatory demands exist for error reporting?
- What is the role of the regulator regarding error reporting?
- What kind of procedures exists to report?
- How does the regulator provide feedback to the hospital regarding mandatory error reports?
- Does any kind of education or courses exist to educate employees in mandatory error reporting and the internal error report system? E.g. what type of events should be reported, how to report. Is the regulator involved?
- How do you think error-reporting influences working on patient safety? How useful is this activity?
- How does the error reporting systems contribute to learning from errors within the hospital?
- How is the obtained information applied to improve patient safety?
- How does the person who reported receive feedback?
- How does the hospital quality committee contribute to learning from errors?

- How does the quality committee manage errors and circulate the information across hospital divisions and wards?
- What is the role of the quality committees at the division level?
- How do they influence the patient safety work?

Experience transfer/learning

- Does any arena exist for experience transfer regarding patient safety issues?
- Does any arena exist for experience transfer between the hospital and the regulator?
- What kinds of activities contribute to experience transfer?
- How does the regulator contribute to experience transfer?
- What kind of barriers hamper experience transfer and learning processes within the hospital?

The regulator – hospital interface, tools, activities

- How do you perceive the regulator's overall strategy? What is the objective?
- How would you characterize the regulatory strategies and tools?
- How do these contribute to improve patient safety and quality of healthcare services?
- Could you say something about advantages and disadvantages?
- How do you think the relationship between the regulator and the hospital should be? (Type of contact, activities, meetings, guidance/control)
- How does the regulator provide advice and guidance? (During system audit and when the hospital asks for guidance)
- How do you think activities between the hospital and regulator affect patient safety processes within the hospital?
- How does the hospital perform proactive risk management to prevent medical error?
- Is this an area in which you have seen changes in past years? How?
- How can the regulator improve the proactive risk management within the hospital?
- What factors do you think are the most important in order to improve patient safety?

Appendix VI

Interview guide – specialized healthcare (middle management, staff level)

Background of the informant

- Age
- Gender
- Education
- Profession
- Number of work hours when you are on duty
- Work experience
- Permanently employed/temporary

Amount and categorization of medical errors/undesired events

- How would you in you own words define medical error in your ward?
- Do you think the other employees and managers at your ward define medical error as you do? What do you think would be different?
- Do you know if medical errors happen within your ward, other wards, within your profession, or other professions? Could you give examples?
- Would you say that some types of medical errors occur more often than others? Which and why?
- Based on the fact that medical errors occur within healthcare – what are your thoughts on the reasons why they occur?
- What kind of situations do you think involve the larges potential of the occurrence of medical errors? (E.g. at the end of the duty, at night, when understaffed, etc.)
- Have you personal experience with medical errors? (Yourself or being around when others have made mistakes)
- How do you report medical error? What kind of routines do you follow?
- Have you ever reported a medical error you or one of your colleagues has committed? Have you ever omitted to report a reportable error?
- In what way are near misses managed? How do you think they should be managed?
- How is the available information about medical errors and near misses used? Is there any kind of feedback to the person who reported or the ward?
- How do you think work experience affect if employees perceive situations as a patient risk? Why and how?
- What kind of use do you find in error reporting? Positive and negative
- What are your thoughts on if error reporting should be open or anonymous?
- What are your thoughts on underreporting? To what degree do you think it exists?

- What do you think are reasons why underreporting might occur? (e.g. fear of media coverage, bad reputation, reprisals, lack of time if they do not have examples themselves)

Human and organizational factors related to managing medical errors

- Are there any circumstances (managers, colleagues, regulators, media etc.) that affect your perception of medical error?
- How do your managers (top, division, middle) encourage you to report medical errors? How are error reports treated?
- Would you say that there is an open climate to discuss medial errors at your ward?
- How are the employees informed about and trained within error reporting?
- If you were going to report an error, when would you do it? Immediately, if you a quiet period on your call, when you are off duty?
- Would you say that new efficiency demands have caused changes in priorities regarding safe patient treatment? Could you give examples?
- Have there been any changes with regards to the workforce situation within your ward the past years? Could you exemplify how that has influences your work situation?
- How does stress affect the occurrence of medical errors and the degree of reporting medical errors?
- What kind of factors are the most present in hampering the management of errors? Why?
- What kind of factors do you think strengthen the management of errors? Why?

Experience transfer related to medical error

- How do employees discuss medical errors within the group and with the managers?
- How does experience transfer take place between you and your most important colleagues/wards that your work depends on?
- Does any experience transfer regarding medical errors take place across wards, departments, and divisions? How does it happen? Formally or informally?
- In what kind of arenas do you discuss issues regarding near misses, medical errors, and patient safety? (Ward meetings, formal meeting within the professions, informal discussions within the professional group etc.)
- How do these arenas work? Is there any difficulties concerning performance, priorities, results etc.?

Power and power relations and their influence on error management

- Do you think some professional groups have a higher degree of error reporting than others? Why?

- Are employees in any kind of way encouraged to suggest improvements of routines and procedures?
- Have you experienced conflicts regarding managerial decisions and guidelines and what you think is the right in order to perform safe patient treatment?
- Do you think there exist any kind of collegial cover-ups or concealment of each other's medical errors?
- What kind of reactions, formal and informal, might occur if you are open and discuss your own and others' mistakes?

The role of the risk regulator regarding management of medical errors

- What kind of relationship exists between your ward and the regulator? In what kind of cases involve the regulator? Who is in contact with the regulator?
- Have you ever been in contact with the regulator? Local level or national level? Why and what was your experience?
- Is there any contact between the ward and the regulator in forms of follow up activities to improve previous medical errors and prevent medical errors?
- How would you say that it is useful for your ward to interact with the regulator (e.g. inspections, inspection reports)? Has this been positive or negative?
- How does the regulator influence the focus of error management? Is there any case that attracted your attention towards specific types of errors more than others?
- Do you know if the regulator has any sanctioning means available? How does that affect your work?
- How do you think the regulator influences the error management within your ward?